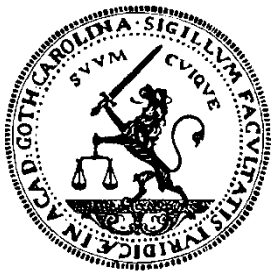

FACULTY OF LAW

Lund University

Irine Urushadze

How to Awaken "Dormant" Pro-Development Provisions of the TRIPS Agreement

JAMM05 Master Thesis

International Human Rights Law and Intellectual Property Rights

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Contents

Summary

It is commonly understood that Intellectual Property Regimes are aimed at protecting private rights and in doing so sometimes neglect public interests. Historically IP systems were considered to allow authors or creators to secure certain monopolies on rights, hence in the 1970s and 1980s the concern over public needs came forward requiring the IP system to respond to it in a way that would stimulate the technological independence of states and therefore development.[1] A little over 20 years ago the TRIPS Agreement, the most relevant global IP Treaty, was created and it endorsed certain developmental issues. However, the global understanding is that TRIPS serves as a tool for development for countries with a certain economic level.[2]

The Development Agenda has become a growing topic in the international arena. However, the understanding of Development has changed over time. If at some point we followed the notion of Development as Growth (economic progress), today we see Development as Freedom and hence when looking at an Intellectual Property regime we cannot neglect the difference of these two concepts. It is argued that IP protection disrupts developing countries to freely pursue their specific economic and social goals.[3] Development Agenda is embedded in the WTO system as well; however it is focused on Simple and Differential Treatment for developing states by allowing them longer transition periods or specific exceptions. Nevertheless the SDT is very narrow while there are higher demands.

This thesis tries to question the common understanding of the IP Regime as subversive to Sustainable Development (or Development as Freedom notion) and proposes the strategic use of the *flexibilities* or other tools enshrined in the TRIPS Agreement for public interests using customary rules of interpretation with the Developmental Goals in mind. The Focal point of articles 7 and 8 (Object and Purpose) of the TRIPS Agreement is Development, however they are more or less "dormant" in current state practice as well as WTO Dispute Settlement practice. This thesis will suggest ways in which they can be "awakened" through customary rules of interpretation or other ways in order to enable the TRIPS Agreement to serve the needs of Sustainable Development.

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[1] See Okediji (Gana) Ruth, *Myth of Development, the Progress of Rights: Human Rights to Intellectual Property and Development,* Law and Policy, Volume 18, Nos. 3&4, July/October 1996. pp. 317-319.

[2] See Ostergard Robert L Jr, *Economic Growth and Intellectual Property Rights Protection.* In *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in A TRIPS-Plus Era,* 2nd Edition, ed. by Gervais Daniel J. Oxford University Press, 2014. pp. 14-16. Ostegard demonstrates several qualitative and quantitative researches done with regards to how domestic IP regimes effect GDP of states, concluding that different states are affected differently based on their development level, see pp. 16-29.

[3] See among others Okediji (Gana), *Myth of Development. Supra* 1. pp. 339-340.

Preface

As a national of a Country with an Economy in Transition (Georgia) understanding Development has been challenging for me, since the common perspective in Georgia is that Development stands for Economic prosperity, but the considerations to social and environmental issues are neglected. At the same time Georgia, much like many other states, faces social challenges. I believe as a more liberal person, that states should limit themselves from regulating private sectors and provide for a free market economy. However, I think that protecting IP Rights requires certain regulatory mechanisms, thus the State has already interfered with the free market and it is acceptable since protecting IP rights does not only serve private rights of authors, but also the greater good of incentivising inventiveness, creation and many other public goods. On the other hand, there are circumstances when a State faces social needs and neglecting them will cause adverse impacts on various issues, including but not limited to Human Rights. This is why I think Sustainable Development is crucial in the modern world and States should be able to pursue such Developmental goals.

I chose this topic because I believe the Intellectual Property Regime is vital for Development (both as a notion of Growth and as Freedom) and it is not a goal in itself, but a means to an end. Thus I wanted to explore what this Regime offers States that face certain needs and how it could serve Development without demolishing Intellectual Property protection.

I am thankful to my supervisor, Peter Gottschalk, for his guidance and assistance throughout my work. I also want to thank my teachers and classmates from the courses on Intellectual Property Law in a Global Perspective and Human Rights Perspectives on Intellectual Property Law. Individual and Group assignments as well as lectures from those courses gave me a new perspective on numerous things allowing me to create this thesis.

I would like to extend my gratitude to my opponent on the defence seminar, Shukria Yusuf Omer, whose thoughtful comments helped me greatly in polishing my thesis and to a colleague, Emil Dirk Conradie, who provided me with relevant contribution despite his busy schedule.

I also thank my husband, Irakli Ksovreli, for the unceasing encouragement and support, as well as important input and feedback throughout my studies and my work on the thesis.

This publication has been produced during my scholarship period at Lund University, thanks to a Swedish Institute scholarship.

List of Abbreviations

CESCR	Committee on Economic, Social and Cultural Rights
CIPR	Commission on Intellectual Property Rights
CL	Compulsory Licensing
DSB	Dispute Settlement Body
DSU	Dispute Settlement Understanding
EC	European Communities
FCTC	Framework Convention on Tobacco Control
FDI	Foreign Direct Investment
GATT	General Agreement on Tariffs and Trade
GC	General Comment
GDP	Gross Domestic Product
GIs	Geographical Indications
HIV/AIDS	Human Immunodeficiency Virus / Acquired Immunodeficiency Syndrome
ICT	Information and Communication Technology
IP	Intellectual Property
IPRs	Intellectual Property Rights
ITC	International Trade Centre
JSC	Joint Stock Company
JTI	Japan Tobacco International
LDC	Least Developed Country
MDGs	Millennium Development Goals
R&D	Research and Development
SAIC	State Administration for Industry and Commerce (of China)

SDG	Sustainable Development Goals
SDT	Special and Differential Treatment
STI	Science, Technology and Innovation
ToT	Transfer of Technology
TPP	Tobacco Plain Packaging
TRIPS	Trade-Related Aspects of Intellectual Property Rights
UN	United Nations
UNCTAD	United Nations Conference on Trade and Development
UNESCO	The United Nations Educational, Scientific and Cultural Organisation
UNICEF	The United Nations Children's Fund
US/USA	The United States of America
VCLT	Vienna Convention on Law of Treaties
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation
WTO	World Trade Organisation

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Introduction

a. Background

On January 1 2015 exactly 20 years had passed since the TRIPS Agreement came into force. This anniversary will bring out a lot of discussion on what the Agreement has achieved, what were its effects and so on. At the same time, 2015 is the deadline for the UN Millennium Development Goals, the most influential Development Document in the world and a new page is turned with the Post-2015 Agenda. These two issues have been linked before and since these two milestones coincide, the interrelationship between the IP Regime and Development will probably become even more topical, discussing what role IP can serve for the current or future Agendas in securing Sustainable Development. Recent studies suggest that there is a possibility for developing countries to respond to TRIPS pressures by embracing its Regime and at the same time "creatively limit" the imposed obligations and the prices associated with them.[4]

b. Research Questions

The main Research Question in this Thesis is *How to use provisions of the TRIPS Agreement for achieving Development Goals?* Additionally, the thesis tries to answer the following questions as well: *How does the Intellectual Property Regime link to Development? What are the tools allowed by the TRIPS Agreement to limit IP Rights and strengthen Development? How would IP-oriented judicial/quasi-judicial institutions react to using these tools?*

c. Purpose

It is frequently considered that the IP Regime is beneficial for certain issues, but it mostly hinders development goals of Developing or Least Developed Countries. The purpose of this Thesis is to demonstrate that the IP regime on its own includes certain tools that could actually help Countries reach their Development goals and solve problems in their Human Rights Agenda. This thesis is aimed at providing information and legal insights to development professionals, human rights activists, academic community or those with some legal background interested in Intellectual Property and its role in Sustainable Development.

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[4] See Okediji (Gana) Ruth L, *TRIPS and Its Methods: The Resilience of Developing Country Implementation of Intellectual Property Norms.* In *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in A TRIPS-Plus Era*, 2nd Edition, ed. by Gervais Daniel J. Oxford University Press, 2014. pp. 242-243.

d. Structure

This thesis consists of three main chapters: the first one deals with the Development issue, where it originates from and where Intellectual Property links with it; in the second chapter the thesis tries to explore what concrete ways exist to help Development using the IP Regime discussing several relevant IP Rights and the tools in the TRIPS Agreement that can be used for pro-development purposes; the last chapter deals with the WTO judicial mechanism and discussing its case law together with the arguments provided in the second chapter, tries to test what would happen if certain tools suggested in this thesis were used by WTO member states.

e. Methodology

This thesis is proposing the ways in which some provisions of the Trade Related Aspects of Intellectual Property Rights Agreement can be enabled to promote Development. For this, reading and interpreting the norms is essential, however certain background needs to be set as well as it must be demonstrated that the interpretation presented can be reasonably applied.

For the reasons above, different chapters of this thesis use different methodology: the first part is mainly a literature review to demonstrate what Development is, how it is defined in different fora and how it relates to IP Rights. However, when discussing the TRIPS Agreement and its pro-development goals, a legally dogmatic method is applied, more specifically interpretative method, to see what is meant in the text of the Agreement using the customary rules of interpretations.

The second part applies interpretative method to discuss different IP Rights and the flexibilities or other tools set by the IP Regime that can be used for Development Goals. This part uses customary rules of interpretation, as prescribed by the Article 3.2 of the Understanding on Rules and Procedures Governing the Settlement of Disputes in the WTO ("The dispute settlement system of the WTO [...] serves [...] to clarify the existing provisions of [the] agreements in accordance with customary rules of interpretation of public international law"), such as the ordinary meaning of the text, preparatory works, subsequent practice and others, to read what is meant by IP norms by looking at the structure, wording and context of the provisions, at the same time certain analytical and critical study is also utilised to strengthen the reasoning and several case studies are presented to support the core arguments. While making interpretations, a Development-oriented perspective is taken, more specifically, TRIPS norms are interpreted with Sustainable Development as a goal in mind.

For doing so the object and purpose (articles 7 and 8 of the TRIPS) of the Agreement are considered as a central issue. In most instances, a positivist approach is utilised, however soft-law instruments are considered for providing stronger interpretations, hence whenever possible normative arguments are put forward.

The last part starts descriptively to build the background, but the main method used is hypothetical suggestion in order to display what could happen if the understanding provided in the Thesis is applied by the TRIPS member states. Three hypothetical cases are described and based on the core arguments of the paper it is shown what political and legal development there can be in the WTO arena.

Since Intellectual Property is a multidimensional and interdisciplinary study the challenge of legally dogmatic or interpretative approaches is a lack of attention to some political, social and economic issues. The line between interpreting the norms and law-making is rather thin and easy to cross, even when customary rules of interpretation are applied. There can be no accurate and decisive recipes. This is why normative considerations need to be brought out to make the interpretive process meet the needs and reflect socio-economic policies or other non-legal considerations. It should be stressed that when discussing TRIPS with a Development lens the *lex ferenda* ("the future law", or more contextually – "as the law should be") approach is also taken, as I suggest understanding the legal norms in a way that is not established with positivist approach. Howeve,r I do not consider how the law should be amended, but rather how the law should be understood, viewed and used. In this regard mere interpretations are not enough, we should fall back on issues like soft-law, justice and global or national policies.

f. Delimitations

This thesis focuses on issues within a certain scope, primarily when discussing the IP Regime, only the TRIPS context is considered, other bilateral, multilateral or national contexts are disregarded. This thesis also discusses the understanding of the Development notion and for the purposes of this work, Sustainable Development will be considered within the term Development, unless otherwise specified in the context. When exploring tools within the TRIPS Agreement only those related to the UN Development Agenda or other understandings of Development discussed in the first chapter are considered. Not all issues arising from the IP-Development linkage are considered, but only those about access to medicines, addressing public health issues caused by tobacco consumption, access to educational materials and socio-economic growth (as achieved by the Geographical Indications regime).

g. Glossary of Key Terms

Certain Terms in this thesis are specific to IP field, making the content more complex and hard to understand for readers not proficient in the field. The Terms below are few most relevant ones. The definitions are taken from WTO and WIPO official webpages, as well as from the CIPR Report.

Bolar Exception / Regulatory Review	An exception according to which a third party is allowed to use patented product without the authorisation of the rightholder. The purpose of the use is obtaining regulatory approval (for example approval to produce and market drugs by the State Authorities).
Compulsory Licence	An act of State granting right to the third party to use patented product without patent rightholder's permission.
Copyright	Right of creators of original literary, scientific and artistic works allowing them exclusivity on their creations. The right exists without any formal requirement (such as registration, although some jurisdictions might require fixation in tangible medium). Copyright prevents unauthorised copying, reproduction, recording, broadcasting, public performance, translation, adaptation.
Doha Declaration	Declaration on TRIPS and Public Health adopted in Doha in 2001 by the Ministerial Meeting of the WTO member states.
Exhaustion (also see First Sale)	Exhaustion of Rights refers to a principle according to which IP Rights of the rightholders are no longer exercisable (exhausted) when the protected product has been put on a market by the rightholder (or any authorised party).
Fair Use / Fair Dealing	An exception to Copyright that allows usage of protected material by third parties for specific purposes or circumstances, such as research, education, library use and other. Fair Use is US Term for the same concept as Fair Dealing.
First Sale	First Sale is a doctrine of the US Law which deals with

	same issue as exhaustion, but mainly with regards to Copyright and Trademark. Thus according to First Sale doctrine, once copyrighted material is sold for the first time, the copyright holder does not have control on sold copy, for instance, it can be resold, rented or lent.
Flexibilities	Flexibilities in IP Law refers to "a degree of room for manoeuvre" (according to WIPO) for the states in implementation of the TRIPS or other WTO and WIPO treaties. TRIPS Agreement Preamble states: "[...] the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base."
Generic Medicine / Generic Drug	Generic product refers to a product that has identical composition (chemical) as the patent-protected product.
Geographical Indication	Name, mostly toponym (name of place), identifying the territorial origin of the product that derive their quality, specific characteristics and other aspects from their geographical origins. The GI can be a toponym as well as term that is associated strongly with a toponym. GI as an IP Right protects the name from being used for products not originated from the region the GI refers to.
National Treatment	Principle entailing the duty of a State to treat nationals (or entities) of another state equally to its own nationals.
Parallel Imports	Parallel Import refers to the process of importing a patent-protected product from a country once it has been put on that country's market legally (by the rightholder or any other authorised party).
Patent	An IP Right which gives its owner exclusivity on invention and the right to prevent unauthorised creation, sale, distribution, importation or any usage for a certain period of time.
Regulatory Review	See Bolar Exception
Research and	A process in industry (such as pharmaceutical, technology or other) leading to innovation, creation or invention of

Development	products and processes; or improvement of the existing ones.
Reverse Engineering	A process when a product is deconstructed, or examined of its composition to recreate (reproduce or copy) it.
Sustainable Development	Development, incorporating economic, human and environmental development, which meets the present needs without compromising future generations to meet theirs.
Trademark	A distinctive sign (name, shape, symbols, letters) allowing the rightholder to be identified as a producer of a product and protect the associated reputation.
TRIPS-Plus / TRIPS+	TRIPS Plus refers to concept of enacting or implementing stronger IP Standards than the ones required by TRIPS. It usually entails Bilateral or Plurilateral agreements that require parties to strengthen their IP laws beyond TRIPS.

1. The Sustainable Development and Intellectual Property - How Do these Two intersect?!

a. What Is Development

United Nations Charter, adopted in 1945, committed member states to a co-operation to achieving "higher standards of living, full employment, and conditions of economic and social progress and development".[5] Although Development was mentioned and positioned in the UN Agenda as early as its conception, it has not been as relevant as it probably deserved to be. It entered the spotlight in 1970s; the maxim "right to development" was coined in 1972.[6] However before 1980-1990s, the Development was mainly understood as matter of economic growth, until Amartya Sen brought in the human dimension to the concept.[7] He argued that Development should be a tool for achieving freedoms people enjoy and at the same time, those freedoms will be means of Development.[8]

The concept of Development has become topical issue in the early 80s of the twentieth century. As stated in the Preamble of the United Nations Declaration on the Right to Development, it "is a comprehensive economic, social, cultural and political process, which aims at the constant improvement of the well-being of the entire population and of all individuals on the basis of their active, free and meaningful participation in development and in the fair distribution of benefits resulting therefrom".[9] The Working Group of Governmental Experts on the Right to Development was operating in 1981-1989 period, goal of which, among others, was to study the scope and contents of the right to development and the most

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[5] United Nations, Charter of the United Nations, October 24, 1945, article 55. Available at: http://www.un.org/en/documents/charter/ [last accessed on May 26, 2015].

[6] See Moyn Samuel. *The Last Utopia. Human Rights in History*, The Belknap Press of Harvard University Press Cambridge, Massachusetts, and London, England. 2010. p. 224.

[7] See Alston Philip, Goodman Ryan. *International Human Rights*, Oxford University Press. 2013. pp. 1516-1517. Also see Chon Margaret, *Intellectual Property and Theories of Developmental Justice.* In *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in A TRIPS-Plus Era*, 2nd Edition, ed. by Gervais Daniel J. Oxford University Press, 2014. p. 257. Chon points out that there is not only the development divide between Developed and Developing countries, but also in understanding Development – "development primarily as economic growth contrasted with development as gains in both economic and social freedoms." The latter is further referred as "Development as Freedom". More on this *infra* 8.

[8] See Sen Amartya. *Development as Freedom,* Oxford University Press, 1999. pp. 36-38.

[9] The United Nations "Declaration on the Right to Development" was adopted by the United Nations General Assembly resolution A/RES/41/128 on December 4, 1986. http://www.un.org/documents/ga/res/41/a41r128.htm [last accessed on May 26, 2015].

effective means to ensure its realisation.[10] The Working Group in one of its very first sessions stressed out:

"[T]he object of the right to development would be the 'integral development' of peoples or States, a concept going **beyond economic growth or development** *per se*. In one view, a legal formulation of the right to development could be the satisfaction of a number of 'basic or fundamental needs' of the individual [emphasis added]".[11] The Commission also claimed:

> "[T]he demands of development cannot justify any derogation from fundamental human rights. [..T]here can be no development without respect for the fundamental rights of the individual, as a national development strategy that rejects civil, political, economic, social and cultural rights would be **the very negation of development** [emphasis added]**"**.[12]

The term itself stands for the act or process of growing or causing something to become more advanced.[13] I consider that it circumscribes the idea of economic, cultural and social progress. A little later of adopting UN Resolution on Right to Development, the "Brundtland Report" coined the term of "Sustainable Development" which was defined as the development that "meets the needs of the present without compromising the ability of future generations to meet their own needs".[14]

Despite all above-mentioned, Development remained to be controversial among scholars, some believed that it could have had negative effect when considering its legality, since the logical user of the right would be State.[15] On the other hand, the same reason might have given Development more relevance. As Bedjaoui put it, "[t]he right to development is a fundamental right, the precondition of liberty, progress, justice and creativity. It is the alpha and omega of human rights, the first

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[10] See the web-page of the UN Office of the High Commissioner: http://www.ohchr.org/EN/Issues/Development/Pages/Documents.aspx [last accessed on May 26, 2015].

[11] UN Commission on Human Rights. Economic and Social Rights. The Working Group of Governmental Experts on the Right to Development. E/CN.4/1489, February 11, 1982. p. 6. http://daccess-dds-ny.un.org/doc/UNDOC/GEN/G82/105/15/PDF/G8210515.pdf?OpenElement [last accessed on May 26, 2015].

[12] *ibid.* p. 11.

[13] The Merriam-Webster Online Dictionary. http://www.merriam-webster.com/dictionary/development [last accessed on May 26, 2015].

[14] Report of the United Nations World Commission on Environment and Development, A/RES/42/187, adopted on 96th plenary meeting 11 December 1987. http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/42/187 [last accessed on May 26, 2015].

[15] See among others Donnelly Jack. *In Search of the Unicorn: The Jurisprudence and Politics of the Right to Development,* 15 Cal. W. Int'l L.J. 473. 1985. pp. 498-499.

and last human right, the beginning and the end, the means and the goal of human rights."[16]

b. *The UN Millennium Development Goals and Linkage with IPRs*

Since the adoption of the Declaration on Right to Development, the issue has been overarching through various political debates, when in 2000 it reached its culmination point by adopting Millennium Development Goals by the United Nations which mainstreamed the subject in almost all UN policies and even beyond.[17] The MDGs include 8 different Goals, 18 targets and 48 indicators.[18] Two Goals are particularly linked to the Intellectual Property Rights: Goal 6 - *Combat HIV/AIDS, Malaria and Other Diseases* and Goal 8 - *Global Partnership for Development*. The latter is divided into 6 targets that demonstrate the linkage even better:

- ✓ *Target 8.A*: Develop further an open, rule-based, predictable, non-discriminatory trading and financial system;
- ✓ *Target 8.B*: Address the special needs of least developed countries;
- ✓ *Target 8.C:* Address the special needs of landlocked developing countries and small island developing States;
- ✓ *Target 8.D*: Deal comprehensively with the debt problems of developing countries;
- ✓ *Target 8.E*: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries;
- ✓ *Target 8.F*: In cooperation with the private sector, make available benefits of new technologies, especially information and communications.[19]

These Targets demonstrate the relevance of Trade to enhance Development and among other issues, Intellectual Property plays important role in reaching Target 8.B, 8.E and 8.F. It has to be noted, that IP might have high relevance for reaching

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[16] Bedjaoui Mohammed, *The Right to Development*, in *International Law: Achievements and Prospects*, Bedjaoui M. (ed.), UNESCO, 1991. p. 1182.

[17] In September 2000, United Nations Millennium Declaration was adopted to create a new global partnership to reduce extreme poverty and set out a series of time-bound targets - with a deadline of 2015 - the Millennium Development Goals (MDGs). More on MDGs can be seen on the official webpage: http://www.un.org/millenniumgoals/ [last accessed on May 26, 2015].

[18] Goals, Targets and Indicators can be seen here: http://www.unmillenniumproject.org/goals/gti.htm [last accessed on May 26, 2015].

[19] For more information on MDGs see *Claiming the Millennium Development Goals: A Human Rights Approach*, HR/PUB/08/3, UN Publication. New York and Geneva, 2008. pp. 1-4.

the Goal 2 (Achieve Universal Primary Education), as well as other goals regarding environmental sustainability, child and mother mortality issues and hunger eradication.[20] This paper will focus on how IP Regime can be used as a tool for the three targets of Goal 8, along with the Goal 6, Target B regarding universal access to HIV/AIDS medication to all. The focus this paper will have on IPs and Education goes a little beyond MDG 2, but it also could be related.

c. WIPO Development Agenda

UN MDGs are not the only issue that links IP Regime to Development Agenda, the General Assembly of World Intellectual Property Organisation established its own Agenda in 2007.[21] The document provides six clusters of Recommendations, with 45 recommendations overall, it also has created Committee on Development and Intellectual Property.[22] The WIPO brought Intellectual property and Development even closer and shifted its IP-Centric role towards pro-development regime. The organisation was initially tasked to "promote the protection of intellectual property throughout the world".[23] However since it became UN Specialised Agency and the New International Economic Order, WIPO's purpose became "promoting creative intellectual activity and for facilitating the transfer of technology related to industrial property to the developing countries to accelerate economic, social and cultural development".[24] Nevertheless one should not understand these changes as putting Intellectual Property aside, on the quite contrary UN-WIPO Agreement quoted above demonstrates that the main task was using IP Regime to achieve development. This idea will be central to this thesis.

The six clusters of the WIPO underline those topical issues that demonstrate the aspects where IP has a potential of enhancing development.

- ✓ *Cluster A:* Technical Assistance and Capacity Building

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[20] WIPO web-page discusses what the organisation has done to help achieving MDGs. Each goal is briefly discussing IP and MDGs relationship. http://www.wipo.int/ip-development/en/agenda/millennium_goals/ [last accessed on May 26, 2015].

[21] Assemblies of the Member States of WIPO, September 24 to October 3, 2007. Geneva. A/43/13 Rev. http://www.wipo.int/edocs/mdocs/govbody/en/a_43/a_43_13_rev.doc [last accessed on May 26, 2015].

[22] See http://www.wipo.int/ip-development/en/agenda/recommendations.html [last accessed on May 26, 2015].

[23] Convention Establishing the World Intellectual Property Organisation. July 14, 1967. Preamble. http://www.wipo.int/treaties/en/text.jsp?file_id=283854 [last accessed on May 26, 2015].

[24] Agreement between the United Nations and the World Intellectual Property Organisation. Entered into force December 17, 1974. Article 1. http://www.wipo.int/treaties/en/text.jsp?file_id=305623#fstar [last accessed on May 26, 2015].

- ✓ *Cluster B:* Norm-setting, flexibilities, public policy and public domain
- ✓ *Cluster C:* Technology Transfer, Information and Communication Technologies (ICT) and Access to Knowledge
- ✓ *Cluster D:* Assessment, Evaluation and Impact Studies
- ✓ *Cluster E:* Institutional Matters including Mandate and Governance
- ✓ *Cluster F:* Other Issues

These Clusters and detailed recommendations thereof were project of growing debate regarding development in different fields. The WIPO Development Agenda can be seen as a result of the trend to discussing IP rights not as an end, but as means of Development.[25] This paper will not take focus on each cluster, but will look at this Development Agenda as an overarching issue and an additional tool to solve the specific problems set out by the thesis.

d. UN Post-2015 Agenda and IPRs Linkage

Since UN Millennium Development Goals are set to be implemented by 2015, there is need to adopt new goals. UN Post-2015 Agenda is still work in progress being one of the most relevant and growing topics in Development debate. The current state of the discussion has set out much wider scope and set of goals, as well as targets for sustainable development.[26] The new agenda is setting out Sustainable Development Goals (SDGs) and is far more ambitious than the MDGs ever were. To my mind the biggest achievement of this movement is inclusion of all countries, not just focus on Developing or Least Developed ones, maybe the biggest problems lie within these group of States, but focusing on "everywhere" has extreme relevance. First of all, looking at the understanding of grouping states creates number of questions. The most focus of MDGs and many other debates were LDCs, while lots of Developing countries and Economies in Transition (or Emerging Economies) were neglected in discussions. Although most targets are still focused on LDCs, it still is a step forward at achieving global sustainable development. Many of the goals are linked with knowledge sensitive issues, such as education, healthcare, technologic progress and others. One of the core issues of Goal 17 is Technology with following targets:

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[25] See Moraes Henrique Choer, Brandelli Otavio. *The Development Agenda at WIPO.* In *The Development Agenda. Global Intellectual Property and Developing Countries,* ed. by Neil Weinstock Netaniel, Oxford University Press. 2009. p. 44.

[26] The list of Goals and Targets can be found on United Nations Department of Economic and Social Affairs administered webpage: https://sustainabledevelopment.un.org/sdgsproposal [last accessed on May 26, 2015].

> "enhance North-South, South-South and triangular regional and international cooperation on and **access to science, technology and innovation, and enhance knowledge sharing** on mutually agreed terms, including through improved coordination among existing mechanisms, particularly at UN level, and through a global technology facilitation mechanism when agreed
>
> **promote development, transfer, dissemination and diffusion of environmentally sound technologies** to developing countries on favourable terms, including on concessional and preferential terms, as mutually agreed
>
> fully operationalize the Technology Bank and STI (Science, Technology and Innovation) capacity building mechanism for LDCs by 2017, and enhance the use of enabling technologies in particular ICT [emphasis added]".[27]

Reaching these particular targets at the very least and many others will be highly dependent on the IP regime, thus raising its relevance for global community.[28]

e. TRIPS - IP Centric Instrument with Pro-Development Purposes?!

> "Recognizing that [the relations of the Parties to the Marrakesh Agreement Establishing the World Trade Organisation] in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, [...], while allowing for the optimal use of the world's resources in accordance with the objective of **sustainable development**, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development [emphasis added]."[29]

The quote from WTO Agreement Preamble proves that Development was one of the central issues on the Agenda when discussing creation of the Organisation.

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[27] *Supra* 26.

[28] More on relevance Intellectual Property for SDGs were emphasised in UN Resolution adopted by the General Assembly on 27 July 2012, *The Future We Want.* A/RES/66/288. particularly paras 73 and 269. http://www.un.org/ga/search/view_doc.asp?symbol=A/RES/66/288&Lang=E [last accessed on May 26, 2015].

[29] Marrakesh Agreement Establishing the World Trade Organisation. April 15, 1994, 1867 U.N.T.S. (hereinafter WTO Agreement). Preamble. https://www.wto.org/English/docs_e/legal_e/04-wto_e.htm [last accessed on May 26, 2015].

The TRIPS Agreement was annexed to this document and it also includes the development issue, but on a different level. Specifically, if WTO Agreement puts Development as a premise of the relations between member states, TRIPS Agreement considers it one of the core values of the IP related norm setting. Specifically, Article 7 (Objectives) sets out what the protection and enforcement of IPRs should be oriented at: "technological innovation and to the transfer and dissemination of technology", "mutual advantage of producers and users", encouraging "social and economic welfare" and last but not least "to a balance of rights and obligations". While Article 8 (Principles) gives member states right to shape IP regulations with high regard to their own interests and necessities to "protect public health and nutrition", "promote the public interest in [...] their socio-economic and technological development" and to "prevent the abuse" of IPRs.[30] These articles confirm that IP is means to an end, not the goal itself.

In view of this background tagging TRIPS Agreement as an IP-Centric instrument should be at least controversial. Even looking back at the history of its drafting suggests that it is hard to claim TRIPS had a goal of pushing Developing world towards something completely unacceptable for them. Peter Yu argues that there are several narratives that can shed the light on how TRIPS came into being. They are controversial and suggest that it could be a product of either "bargain" between North and South to get more IP protection for Developed countries while providing better access to their market for Developing countries' agriculture products; or it could have been "coerced" to Developing world with no regards to their needs; it could have been caused by the "ignorance" of less developed states towards IP Regime; or the same developing world might have been acting based on their self-interest to gain access to IP creations by adhering to TRIPS.[31] These different "narratives", some of which are challenged by historical facts, propose that there is no one way to look at the Agreement. It could have been something Developing world was reluctant to agree, but at the same time, judging from the way it all turned out it can still serve their specific interests. It is historically supported that the articles quoted above regarding objectives and principles of the TRIPS were included based on concerns of Developing countries.[32]

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[30] See World Trade Organisation, the Trade-Related Aspects of Intellectual Property Rights Agreement, Annex 1C of the Marrakesh Agreement Establishing the World Trade Organisation. 15 April 1994. Articles 7 and 8. http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm [last accessed on May 26, 2015].

[31] See Yu Peter K. *TRIPS and Its Discontents,* 10 Marq. Intell. Prop. L. Rev. 369 2006. pp. 371-379. Also see Gervais Daniel J. *IP Callibration.* In *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in A TRIPS-Plus Era,* 2nd Edition, ed. by Gervais Daniel J. Oxford University Press, 2014. p. 90.

[32] See Gervais Daniel J. *Intellectual Property, Trade and Development: The State of Play,* 74 Fordham L. Rev. 505, 2005-2006. pp. 507-508.

It is one thing to look in the past for finding answers to what role TRIPS can have in the Development process, but twenty years in this century is quite long to suggest that same narrative should be followed. TRIPS, as any other international legal document needs to be interpreted based on widely accepted rules, specifically the VCLT which, based on the WTO DSB case law, is considered to be valid and relevant rules of interpretation for this Agreement.[33] The article 31 of the VCLT provides that the context and object and purpose of the treaty should be considered for defining its ordinary meaning.[34] "[A] treaty interpreter is required to have recourse to context and object and purpose to elucidate the relevant meaning of the word or term. This logical progression provides a framework for proper interpretative analysis. At the same time, it should be kept in mind that treaty interpretation is an integrated operation, where interpretative rules or principles must be understood and applied as connected and mutually reinforcing components of a holistic exercise."[35] It is essential to point out that WTO DSB has recognised the relevance of interpreting WTO Agreement "in accordance with the objective of sustainable development".[36]

In the following chapter these rules of interpretation will be used to analyse specific regulations in the TRIPS Agreement that will demonstrate, how it can enhance the current Development Agenda with regards to access to education materials, access to medicines, addressing pressing public health concerns and the ability to elevate economic growth.

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[33] See Appellate Body Report, *India–Patent Protection of Pharmaceutical and Agricultural Products*, WT/DS50/AB/R, December 19, 1997. para. 46. Panel Report, *Canada–Patent Protection of Pharmaceutical Products*, WT/DS114/R, March 17, 2000. Particularly paras 7.14-7.26. Appellate Body Report and Panel Report, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/9, May 20, 1996. pp.16-20.
Also regarding the rules of interpretation and their role in WTO DSU see Van Damme Isabelle, *Treaty Interpretation by the WTO Appellate Body*, The European Journal of International Law Vol. 21 no. 3, 2010. pp. 605-648. "In WTO dispute settlement, the first function of treaty interpretation is clarification of a complex network of WTO covered agreements, enabling panels and the Appellate Body to resolve disputes between WTO members about the interpretation and application of those agreements." p. 641.

[34] United Nations, *Vienna Convention on the Law of Treaties*, May 23, 1969. available at: https://treaties.un.org/pages/ViewDetailsIII.aspx?src=TREATY&mtdsg_no=XXIII-1&chapter=23&Temp=mtdsg3&lang=en [last accessed on May 26, 2015].

[35] Appellate Body Report, *United States – Continued Existence and Application of Zeroing Methodology*, WT/DS350/AB/R, February 4, 2009. para. 269.

[36] Appellate Body Report, *United States — Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R, October 12, 1998. para. 153.

2. How would IP Regime Help Development?

> *The WTO's TRIPS Agreement [...] strikes a carefully-negotiated balance between providing intellectual property protection [...] and allowing countries the flexibility to ensure that treatments reach the world's poorest and most vulnerable people. Countries must feel secure that they can use this flexibility."*[37]
>
> *Mike Moore, WTO Director General*

IP rights are means of technological advancement, which in turn is one of the most important elements at reaching development - it develops healthcare by creating pharmaceutical and technological products; advances quality of food and technologies to harvest food; improves education capacity by creating learning materials and so on. Some scholars claim there are two groups of IPRs: one is composed of rights that stimulate inventive and creative activities and another incorporates rights that resolve information discrepancies by attribution powers.[38] Patents and copyright for instance, belong to group one, as they confer exclusive market power to the rightholders, while geographic indications or trademarks are part of second group, since they do not protect rightholders from copying *per se*, but they allow consumers to attribute goods to certain qualities.[39] Thus it is indisputable that at least first group of IPRs are relevant part of technological advancement and innovation, which in turn promotes array of sustainable development aspects. "If the system overprotects, intellectual creators will not have enough raw materials to develop their creations and the public will not have adequate access to needed information and knowledge. In contrast, if the system underprotects, intellectual creators will not have adequate incentives to create."[40]

Despite above mentioned, IP Regime does impede achieving certain goals, such as access to those IP protected goods. For instance, a 20-year long Patent protection of a specific drug means its creator has monopoly and full control over it, thus pricing it in a way creator sees fit. Usually such pricing covers R&D costs of invention, which makes the price much higher than it actually costs to produce

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[37] *Moore: countries must feel secure that they can use TRIPS' flexibility.* June 20 2001. Available at: https://www.wto.org/english/news_e/news01_e/dg_trips_medicines_010620_e.htm [last accessed on May 26, 2015].
[38] Fink Carsten, Maskus Keith E. *Intellectual Property and Development. Lessons from Recent Economic Research.* World Bank and Oxford University Press. 2005. pp. 174-175.
[39] *ibid.*
[40] Yu Peter K, *Trips and Its Discontents. Supra* 31. p. 382.

the product.[41] Such prices are rarely affordable for the developing world population. This is one of the reasons why scholars consider less protection for IPRs are what Developing and particularly Least Developed Countries need.[42] At the same time, some authors suggest that "IPR protection is not always enacted as part of sound economic policy, but rather as a result of political pressure."[43]

At the same time the developing and particularly LDCs have a long-term objective of achieving progress towards agricultural self-sufficiency and the stimulation of commercial and industrial activity.[44] These countries have the need for not only access to affordable products, but also to knowledge and capacity. MDGs focus on benefits to technological innovation for a good reason and I believe that IP Regime itself has solutions for the problems it allegedly causes. In the following subchapters few IP rights will be considered with regards to most problematic issues.

a. Patent and Health Care

How Patent rights relate to development, particularly health care issues is not a new topic for legal scholarship.[45] However, there are specific details that need to be discussed with different angle. The previous chapter mentioned how TRIPS objectives and purposes are worded in a pro-development way, these two articles could be the key to exploring how Patent rights can be means to solving public health concerns most developing and particularly least developed countries face.

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[41] For example in pharmaceutical production price includes production and R&D costs, studies suggest that production of pharmaceuticals are relatively low, while R&D costs are considerably high. See Herper Matthew "The Cost of Creating a New Drug Now $5 Billion, Pushing Big Pharma to Change" Forbes.com, August 11, 2013. http://www.forbes.com/sites/matthewherper/2013/08/11/how-the-staggering-cost-of-inventing-new-drugs-is-shaping-the-future-of-medicine/ [last accessed on May 26, 2015].

[42] "Standards of IP protection that may be suitable for developed countries may cause greater costs than benefits when applied in developing countries which must rely in large part on knowledge or products embodying knowledge generated elsewhere to satisfy basic needs and foster their development." Commission on Intellectual Property Rights. *Integrating Intellectual Property Rights and Development Policy.* Report of the Commission on Intellectual Property Rights (hereinafter CIPR Report) London. September 2002. pp. 5-6. http://www.cipr.org.uk/papers/pdfs/final_report/CIPRfullfinal.pdf [last accessed on May 26, 2015].

[43] Ostergard, *Economic Growth and Intellectual Property Rights Protection. Supra* 2. p. 4. He also believes that Developing Countries as well as LDCs face international pressure from the Developed World and Industries to pursue stronger IP protection. See pp. 30, 40-41.

[44] See *WIPO Intellectual Property Handbook: Policy, Law and Use.* 2004. p. 163. http://www.wipo.int/about-ip/en/iprm/ [last accessed on May 26, 2015].

[45] For more discussion see Helfer Laurence R., Austin Graeme W. *Human Rights and Intellectual Property. Mapping the Global Interface*, Cambridge University Press, May 2011. Chapter 2, pp. 90-170. Also see the web-page of the WTO on MDGs, Access to Medicines: https://www.wto.org/english/thewto_e/coher_e/mdg_e/medicine_e.htm [last accessed on May 26, 2015].

WTO members have agreed that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health and that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.[46] Although this affirmation was made by the soft-law instrument,[47] we should closely look at the wording of the Declaration: "Agreement **does not** and **should not** prevent members [emphasis added]". The "does not" words clearly demonstrate that the Declaration creates nothing new, but provides strengthening of the existing regulations and reminds member states or anyone else that this is embedded in the TRIPS Agreement. While "should not" could be understood as new normative statement creating certain sets of obligations. Then again, "should not" is also a tool of reaffirming the previous statement. Looking at other statements in the Doha Declaration we will clearly see that it creates very few new duties and is more of a reminder for member states what possibilities lie within the TRIPS Agreement. Therefore, claiming that Doha Declaration is merely a soft-law instrument and has limited or no normative effect is not a strong argument. At the same time, VCLT quoted above provides a tool for interpretation when "Any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions" should be taken into account.[48] Hence, Doha Declaration is at the very best an interpretative tool for TRIPS Agreement asserting existing law. The article 8 of the TRIPS agreement as mentioned above, also recognises the importance of protection of public health as a principle (article 8.1), therefore while interpreting the scope of intellectual property rights, the goal of protection of public health should be cardinal based on the principles of the same Agreement.[49]

It should be noted that July 1, 2021 is the deadline for the Least Developed Countries to adopt all minimum standards set out by TRIPS Agreement regarding Pharmaceutical Patent protection.[50] Although it might seem that LDCs will face

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[46] Declaration on the TRIPS Agreement and Public Health. Adopted on 14 November 2001. WT/MIN(01)/DEC/2. 20 November 2001. Paragraph 4.

[47] See Boyle Alan, *Soft Law in International Law-Making.* In *International Law*, 3rd Edition, ed. by Evans Malcolm, Oxford University Press, 2010. pp. 124-125.

[48] VCLT quoted *supra 34.* Article 31.3.a.

[49] See Howse Robert, *The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times*. The Journal of World Intellectual Property. Vol.3, Issue 4. July 2000. p.504.

[50] "Least developed country Members shall not be required to apply the provisions of the Agreement, other than Articles 3, 4 and 5, until 1 July 2021, or until such a date on which they cease to be a least developed country Member, whichever date is earlier." Council for Trade-Related Aspects of Intellectual Property Rights. IP/C/64. June 12, 2013 (13-3064). This transition period has been extended twice for all LDC members in response to specific requests. The TRIPS Council extended original transition period enshrined in TRIPS Agreement Article 66.1 (which was 10 years from the general application of one year from the date of the entry into force of the Agreement, thus by January 1, 2006) on 29 November 2005, by above mentioned decision, it extended this further until 1 July 2021.

more barriers in achieving their development, the same agreement provides for few possibilities, or more precisely, *flexibilities*, on the way towards development.

The Patent rights, for instance, themselves are a tool of development as they are incentives for technological innovation. However when their monopolistic features become a hindering factor, we must seek for other means of Technology Transfer (ToT). There are formal and informal means of ToT.

Formal	Informal
Trade in goods and services causing spillover of knowledge	Imitation and Reverse Engineering
FDI - control over knowledge stays with the rightholder, but small spillover takes place	Information apprehended from Patent Applications
Licensing - rightholder willingly gives up the knowledge, high level of spillover and ToT	Hiring competitor's employees
flexibilities from TRIPS	

Figure 1. Formal and Informal means of Transfer of Technology

Since FDIs, Trade in goods and services and Licensing is all dependent on rightholders willingness, we need to focus what countries can do when the willingness is not present. *Flexibilities* are means in the hand of the Government. It has been suggested that global public policies should balance the private rights and public health interests.[51]

i) Compulsory Licensing

TRIPS Agreement includes several *flexibilities* when it comes to Patent. Article 31 is one of the most relevant one of them. The text of the Agreement does not mention "compulsory licensing" with regards to Patent or any other right (except of prohibiting CL of Trademarks by article 21). It is however included in the provisions of article 31, which is one of the most detailed article in the whole agreement providing step-by-step guide of how the member states can use patented product without authorisation of the right holder.

- authorisation shall be considered on its individual merits;
- such use may only be permitted

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also: More on meeting the needs of LDCs by TRIPS agreement: http://www.wto.org/english/tratop_e/trips_e/ldc_e.htm [last accessed on May 26, 2015].

[51] See Miguel Pablo Zapatero, *Trade in Generics v. World-Scale Market Segmentation: Market-Driven Solutions to the 'Paragraph 6' Issue,* Journal of World Trade 48, no. 1 (2014). pp. 81-82.

- prior to such use, the proposed user has made efforts to obtain authorisation from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. OR
- there is a case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. Right holder shall be notified as soon as reasonably practicable. OR
- In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

- the scope and duration of such use shall be limited to the purpose or authorisation and involving judicial or other independent review;
- such use shall be non-exclusive;
- such use shall be non-assignable;
- use should be predominantly for domestic market;
- the right holder shall be paid adequate remuneration subject to judicial or other independent review;
- the alternative use is allowed including for non-domestic markets if it is a remedy practice determined after judicial or administrative process to be anti-competitive.

Although TRIPS agreement limits member states in using CL, it still provides a very efficient possibility to use IP Regime for their benefit. By CL member state can "take away" certain exclusive rights from the titleholder. The most undebated example would be when a patent-holder owns exclusive rights of a drug, that has potential of saving lives, but the owner refuses to produce and sell the product.[52] The State can get involved and license the drug to a willing producer without original patent-holder's permission.

ii) Licensing for Countries with Limited or No Manufacturing Capacity

The regulations mentioned above regarding compulsory licensing fail to be efficient for those Developing and particularly Least Developed Countries that

[52] For instance Brazil maintains a local working requirement, which means that in case a patent right holder does not utilise the granted rights locally the State is allowed to use Compulsory Licensing. See more in Okediji (Gana) Ruth L. *Trips and Its Methods: The Resilience of Developing Country Implementation of Intellectual Property Norms.* In *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in A TRIPS-Plus Era*, 2nd Edition, ed. by Gervais Daniel J. Oxford University Press, 2014. p. 248.

lack the capacity to manufacture patent-protected goods. The whole idea of CL rests on the premise, that once Government Authorities give the licence to a third party, the third party can either reverse-engineer the product, or use the information from patent application or use any other means otherwise usually considered illegal to produce the same product. Therefore, the country needs to have manufacturing capacity.

Since the biggest problem in the Developing world is manufacturing capacity, most tools provided by article 31 of the TRIPS might not be useful. This is one of the reasons, why Doha Ministerial Declaration stressed this issue.[53] As a result of Ministerial call for a solution to this problem, WTO General Council adopted the so called "paragraph 6 solution", waiving the requirements of article 31.f. of the TRIPS and allowing CL for non-domestic markets.[54] The procedure enshrined in this decision has been deemed overly complicated and inefficient.[55]

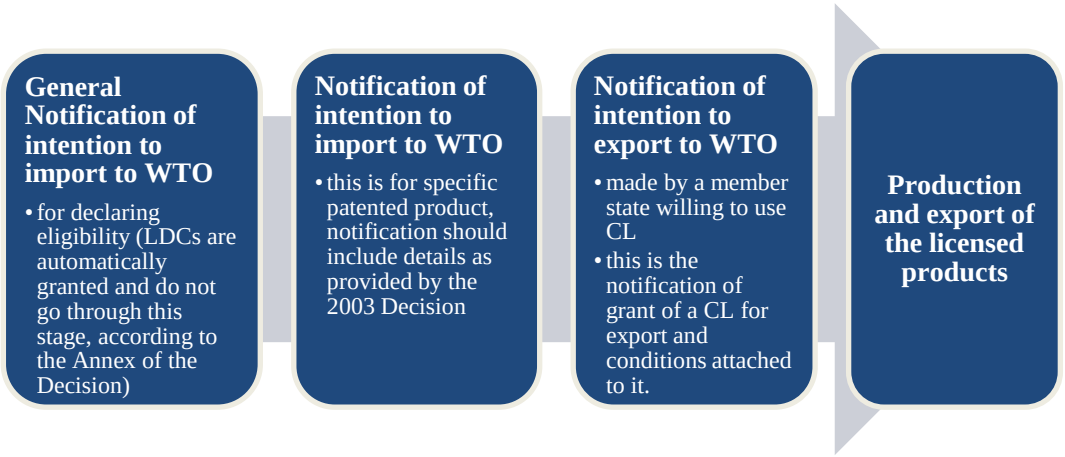

Figure 2. How export of Pharmaceuticals can happen according to Paragraph 6 System[56]

[53] "We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement." *Doha Declaration. Supra* 46. para 6.
[54] WT/L/540, *Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, Decision of the General Council of WTO, 30 August 2003. http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm [last accessed on May 26, 2015]. It has to be noted, that an Amendment of the TRIPS Agreement has been drafted and circulated which is supposed to replace the current "paragraph 6 solution" making it a part of the Agreement. However the Amendment has not been accepted by two thirds of WTO members and therefore is not in effect. The deadline to submit formal acceptance has been extended to December 31, 2015. See more details at the WTO webpage: https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm [last accessed on May 26, 2015].
[55] See Miguel, *Trade in Generics v. World-Scale Market Segmentation. Supra* 51. pp. 88-92.
[56] See more details in Correa Carlos M. *Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, World Health Organisation, Drug Action Programme of the Department of Essential Drugs and Medicines

This solution was "forced" by the understanding that CL is only allowed for domestic markets. However, the reading of article 31.f does not provide this understanding. The language used by TRIPS is following: "[a]ny such use shall be authorized **predominantly** for the supply of the domestic market of the Member authorizing such use" [emphasis added]." The word "predominantly" means "for the most part; mainly".[57] Interpreting it as a prohibition to use CL for non-domestic markets is not provided by the WTO regulations or its case law. Considering the *Doha Declaration* and political willingness of member states to reaffirm that public health agenda should be included in TRIPS interpretation, interpreting article 31.f of the Agreement should also be made in a way that would not limit member states from using CL in any way to promote public health agendas. The fact that the "paragraph 6 solution" has not been used should not be understood that legal means do not exist. It merely means that they need to be more efficient and used more bravely.[58] The current shift of the Agendas and the emergence of the Development as Freedom discourse as opposed to Development as Growth, suggest that if states choose to utilise CL for non-domestic markets, they might succeed in doing so without facing restraints from WTO DSU. Chapter 3 of the Thesis will discuss the issue in more depth.

iii) Exceptions

Article 30 of the TRIPS Agreement allows the members to "provide limited exceptions" to patent rights, however they should not unreasonably "conflict with a normal exploitation" or "prejudice the legitimate interests" of the rightholder.

Policy, April 2004. pp. 39-43. The figure demonstrates the procedure Member State of the WTO should follow to use "paragraph 6 solution" http://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf?ua=1 [last accessed on May 26, 2015].
The chart is quoted from the Paper written for Lund University course Human Rights Perspectives on Intellectual Property Law (JAMR26). Urushadze, Irine. *Compulsory Licensing of Pharmaceuticals - a Way to Secure Health Protection?!* 2014. Unpublished, with the author.

[57] Merriam-Webster Online Dictionary. http://www.merriam-webster.com/dictionary/predominantly [last accessed on May 26, 2015].

[58] So far there is only one case when States used the "solution", when Canada and Rwanda followed all steps required by the WTO Council Decision to export HIV/AIDS generic drug from Canada to Rwanda. See more details in *Canada Issues Compulsory Licence For HIV/AIDS Drug Export to Rwanda, In First Test Of WTO Procedure*, Bridges, Volume 11 - Number 32. September 26, 2007. http://www.ictsd.org/bridges-news/bridges/news/canada-issues-compulsory-licence-for-hivaids-drug-export-to-rwanda-in [last accessed on May 26, 2015].
Another case between Nepal and India merely emerged and was never finalized, since Nepal, the importing country, refused to grant CL and did not notify TRIPS Council that it was intended to avail itself of the "solution". See Miguel, *Trade in Generics v. World-Scale Market Segmentation. Supra* 51. p. 88.

The article underlines that "legitimate interests of third parties" should also be taken into account.

The exceptions that are mostly used by member states are *experimental (research)* exceptions. They refer to the research done on the patented product and number of countries recognises such research to be allowed use.[59] "A first-best patent policy provides investors with an incentive to invest while not limiting any knowledge spill-overs that will have only a small effect on this incentive to invest."[60] The *regulatory review*, also called *Bolar Exception*[61] is an exception explicitly affirmed by the WTO DSB.[62] Canadian Patent Act allowed the use of a patented product for testing that was required for the marketing approval procedures. This meant that anyone could conduct research on the product 6 months prior to the expiry of protection term of patent (20 years), thus enabling them to produce and stockpile the product and receive marketing approval while the original rightholder still enjoyed monopolistic benefits and once the period for that benefit was over competitor could enter the market right away. WTO DSB Panel used articles 7 and 8 of the TRIPS to interpret the scope of "limited exception" provided by article 30 of the Agreement and considered Canadian regulations in line with IP Regime established by the TRIPS. It has to be underlined that the Panel Report was made a year before Doha Declaration was adopted, and yet the Panel stressed that TRIPS interpretation should be done bearing in mind objectives and purposes of the Agreement.

The case has been debated and considered an activism from the Panel both welcomed and condemned in the scholarship.[63] The case has huge relevance and potential for developing world (mainly with certain manufacturing capacities) and can be operated further, helping promote access to necessary pharmaceutical (and any other) products. It should be underlined that Article 30 itself pinpoints towards legitimate interests of the third parties, which gives broad margin of

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[59] See WIPO Standing Committee on the Law of Patents. Twentieth Session. January 27 to 31, 2014. *Exceptions and Limitations to Patent Rights: Experimental Use and/or Scientific Research.* SCP/20/4. November 18, 2013.

[60] Dent Chris, Jensen Paul, Waller Sophie, Webster Beth, *Research Use of Patented Knowledge: A Review*, OECD Directorate for Science, Technology and Industry (STI), STI Working Paper 2006/2. 2006. p.12.

[61] The name comes from *Roche Products Inc v Bolar Pharmaceutical Co.* 733 F 2d 858, 863. Federal Circuit. 1984.

[62] Panel Report, *Canada–Patent Protection of Pharmaceutical Products*, WT/DS114/R, March 17, 2000.

[63] See Correa, Carlos M. *The TRIPS Agreement and Developing Countries*. pp.430-432. Available at http://web.cenet.org.cn/upfile/109807.pdf [last accessed on May 26, 2015].
Also Howse Robert. *The Canadian Generic Medicines Panel. Supra* 49. pp. 493-507. The latter considered that Panel had failed to give TRIPS agreement more balancing weight with regards to interests of right-holders and state's socio-economic interests.

appreciation to the countries in deciding when and how to use exceptions allowed by the TRIPS Agreement.

b. Copyright and Education

Copyright may be mostly seen with regards to access to culture, since it protects mainly cultural and artistic works.[64] However the link between education and copyright is also strong and quite old. Statute of Anne, the document that is considered one of the first legal acts establishing Intellectual Property Regime and definitely the first Copyright document was named "An Act for the Encouragement of Learning".[65] Other legal documents also underline the relevance of education regarding the Copyright system.[66]

Education is probably the most relevant tool in the 21st century world, where knowledge is the greatest power. Almost all IP Rights are knowledge-based, which means creating Intellectual Property goods requires knowledge. Thus a circle is created: IP creates knowledge goods, required to gain more knowledge which in turn is necessary to create IP goods. The question is, whether IP Regime can be used for enhancing education in developing and not only the developing countries. The Committee on Economic Social and Cultural Rights claimed in General Comment that education is "primary vehicle by which economically and socially marginalized adults and children can lift themselves out of poverty".[67]

> "access to books and materials is important for [...] the education system [...]. Developing countries need educated people such as doctors, nurses, lawyers, scientists, researchers, engineers, economists, teachers and accountants. Without people skilled in these professions and a system of life-long learning and education, developing countries will be less able to absorb new technologies, generate innovation, and compete in the global knowledge economy. For example, even if developing countries can

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[64] See Helfer, Austin, *Human Rights and Intellectual Property*. *Supra* 45. Chapters 3 and 4. at pp. 171-363.

[65] *An Act for the Encouragement of Learning, by vesting the Copies of Printed Books in the Authors or Purchasers of such Copies, during the Times therein mentioned*. 1710. Commonly referred to as the "Statute of Anne". Full text can be accessed here: http://www.copyrighthistory.com/anne.html [last accessed on May 26, 2015].

[66] See Constitution of the United States of America. Article 1. Section 8. September 17, 1787. "The Congress shall have Power [...t]o promote the **Progress of Science and useful Arts**, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries [emphasis added]."

[67] UN Committee on Economic, Social and Cultural Rights (CESCR), *General Comment No. 13: The Right to Education (Art. 13 of the Covenant)*, 8 December 1999, E/C.12/1999/10, December 8, 1999. para 1.

obtain cheap medicines they will still need trained doctors and nurses to administer them properly in order to save lives."[68]

The scholarship on the relevance of education for achieving development is overwhelming and needs not to be dwelled upon.[69] UN MDG 2 calls for achieving universal primary education, it does not seem to relate with copyright, however access to teaching materials is essential feature of the access to education.[70]

It is relevant that each student has access to a textbook; however, "[t]extbooks are a rare commodity in most developing countries. One book per student (in any subject) is the exception, not the rule, and the rule in most classrooms is, unfortunately, severe scarcity or the total absence of textbooks."[71]

i) Fair Use / Fair Dealing

The TRIPS Agreement offers certain *flexibilities* in Copyright Regime as well, particularly the "Fair Use" or "Fair Dealing" doctrine incorporated from the Berne Convention.[72] This doctrine is considered a balancing tool between the rightholders' interests and social goal of knowledge dissemination, allowing the member states to freely decide when special use is allowed, such as copying for personal use, research, education, archiving, library use and news reporting.[73] CIPR Report summarises few conditions that are more or less universal in allowing the "fair use" in national legislatures:

- "The purpose and character of the use – copying must be for private, non-commercial purposes. Only single or a small number of copies may be reproduced.

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[68] CIPR Report. *Supra* 42. p. 103.
[69] See Helfer, Austin. *Supra* 45. *at* pp. 320-332 summarizing most relevant arguments for the relevance of Education and its impact on exercising other rights, as well as reaching development.
[70] See CESCR GC No.13. *Supra* 67. para 6. "[E]ducation in all its forms and at all levels shall exhibit the following interrelated and essential features: [...] Availability. Functioning educational institutions and programmes have to be available in sufficient quantity within the jurisdiction of the State party. What they require to function depends upon numerous factors, including the developmental context within which they operate; for example, all institutions and programmes are likely to require [...] teaching materials." Also, UNICEF (UNESCO), *A Human Rights-Based Approach to Education for All.* 2007. pp. 56 and 63. http://www.unicef.org/publications/files/A_Human_Rights_Based_Approach_to_Education_for_All.pdf [last accessed on May 26, 2015].
[71] Askerund Perille, *A Guide to Sustainable Book Provision,* UNESCO. 1997. p. 17. available at: http://www.unesco.org/education/blm/chap1_en.php [last accessed on May 26, 2015].
[72] See Berne Convention for the Protection of Literary and Artistic Works. Adopted at Paris on July 24, 1971. Article 9. paragraph 2. The full text of the Convention available at: http://www.wipo.int/treaties/en/text.jsp?file_id=283698 [last accessed on May 26, 2015].
[73] CIPR Report *supra* 42. p. 100.

- The proportion of the work that is copied – copies should be made only of parts of the work. Complete works may be copied only where originals are not available on the market.
- Copies of hard copy works may typically be produced only by reprographic processes. There is also some freedom to make copies of electronic works as, for example, for time-shifting of TV programs or archiving of computer software.
- If there are exemptions for the benefit of libraries and archives, those institutions must be accessible to the public and act in a non-commercial way.
- The legitimate interest of the right-holder must be taken into account – the effect on the potential market for the work"[74]

ii) Exhaustion / First Sale

"Exhaustion" or "first sale" (as called in the US) doctrine incorporates legal regime, when copyright is no longer considered exercisable on a product placed on the market by the rightholder or any other authorised party. According to the Article 6 of the TRIPS Agreement, the issue is completely up to member states to decide and the Agreement governs nothing to address the exhaustion of IPRs.[75] In this subchapter I will not discuss the different exhaustion regimes, but will focus on a case from the recent, very debated US Supreme Court Case *Kirtsaeng v. John Wiley & Sons, Inc.*[76] The case initiated in 2008 by John Wiley & Sons Inc. (hereinafter Wiley) against a Thailand native Supap Kirtsaeng who was selling textbooks, some copyrighted by Wiley, produced outside the US, marketed exclusively for foreign markets.[77] Wiley claimed that this was the copyright infringement and the sale was not authorised in the US. The Supreme Court however, relying heavily upon the interpretation tools to define what is governed under the first-sale doctrine, held that once a tangible copy is purchased anytime, even outside the US, the copyright is exhausted and the rightholder loses control over the resale of the same copy (international exhaustion). The Court thus ruled that once a copy is sold in a foreign country, it is considered exhausted in the US as well.

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[74] *Supra* 73.
[75] See TRIPS Agreement. Article 6.
[76] *Kirtsaeng v. John Wiley & Sons, Inc.* 568 U. S._(2013). Docket No. 11-697, Opinion entered March 19, 2013. http://www.supremecourt.gov/opinions/12pdf/11-697_4g15.pdf [last accessed on May 26, 2015].
[77] Case origins and some details can be seen on CNN news-story *Supreme Court to Hear Arguments in Case of Student Who Resold Books*. By Bill Mears, October 27, 2012. Available at: http://edition.cnn.com/2012/10/26/justice/court-student-copyright/index.html?iref=obnetwork [last accessed on May 26, 2015].

The judgement had huge impact on not just users and retailers, but especially libraries, which were represented in the case by *amicus curiae* reflecting the threats or benefits the judgement could impose upon them.[78] The judgement has been analysed in number of ways, but it remains extremely relevant for book lending purposes and was claimed to be a complete victory for libraries: "The decision eliminates the uncertainty about the permissibility of libraries' importing and circulating materials manufactured abroad".[79]

The First Sale doctrine thus allows access to cheaper textbooks, but the impact is larger on developed country consumers or libraries, such as US in this case. However, the fact that TRIPS gives full discretion to the member states on first sale / exhaustion doctrine allows developing world to think how to exercise this discretion in a more pro-development manner. Apparently, developed legal system has found way to promote more access, thus it can be operational in other contexts as well. The existence of copyright ensures that there always is an interest to create a knowledge good (book in this case), while the exceptions allow more access to such good.

iii) Compulsory Licensing

The problem of access to textbooks was earlier pushed by the developing countries up on the agenda of IP Regime with the result of 1971 Appendix to the Paris Act Revision of the Berne Convention, which was deemed "complex" and "arcane".[80] The so called *Berne Appendix* is aimed at allowing developing states to use an exception of copyright, which we may call Compulsory Licensing of Copyright, allowing them to translate or otherwise reproduce the original work.[81] According to *Berne Appendix*, under certain situations, when prior negotiations with rightholder to obtain permission for translation or reproduction have failed, a developing country may apply for a compulsory licence to translate or to

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[78] Among others, briefs of *amicus curiae* were made by American Library Association, eBay inc, Association of Art Museum Directors and other relevant stakeholders. The list of briefs is available here: http://www.supremecourt.gov/Search.aspx?FileName=/docketfiles/11-697.htm [last accessed on May 26, 2015].

[79] Band Jonathan, Issue Brief, *The Impact of the Supreme Court's Decision in Kirtsaeng v. Wiley on Libraries.* By Library Copyright Alliance, American Library Association, Association of Research Libraries, Association of College and Research Libraries. April 2, 2013. p. 14. available at: http://www.librarycopyrightalliance.org/bm~doc/issue-brief-kirtsaeng-post-analysis-02apr13.pdf [last accessed on March 20, 2015].

[80] See Chon Margaret, *Copyright and Capability for Education: an Approach "from below".* In *Intellectual Property and Human Development.* ed. Wong Tzen, Dutfield Graham. Cambridge University Press. 2011. pp. 229-230.

[81] See Appendix to Berne Convention for the Protection of Literary and Artistic Works. Adopted at Paris on July 24, 1971. The full text of the Convention with the appendix is available at: http://www.wipo.int/treaties/en/text.jsp?file_id=283698 [last accessed on May 26, 2015].

reproduce protected works at a reasonable price. The more detailed step-by-step guide is displayed in *figure 3* below.

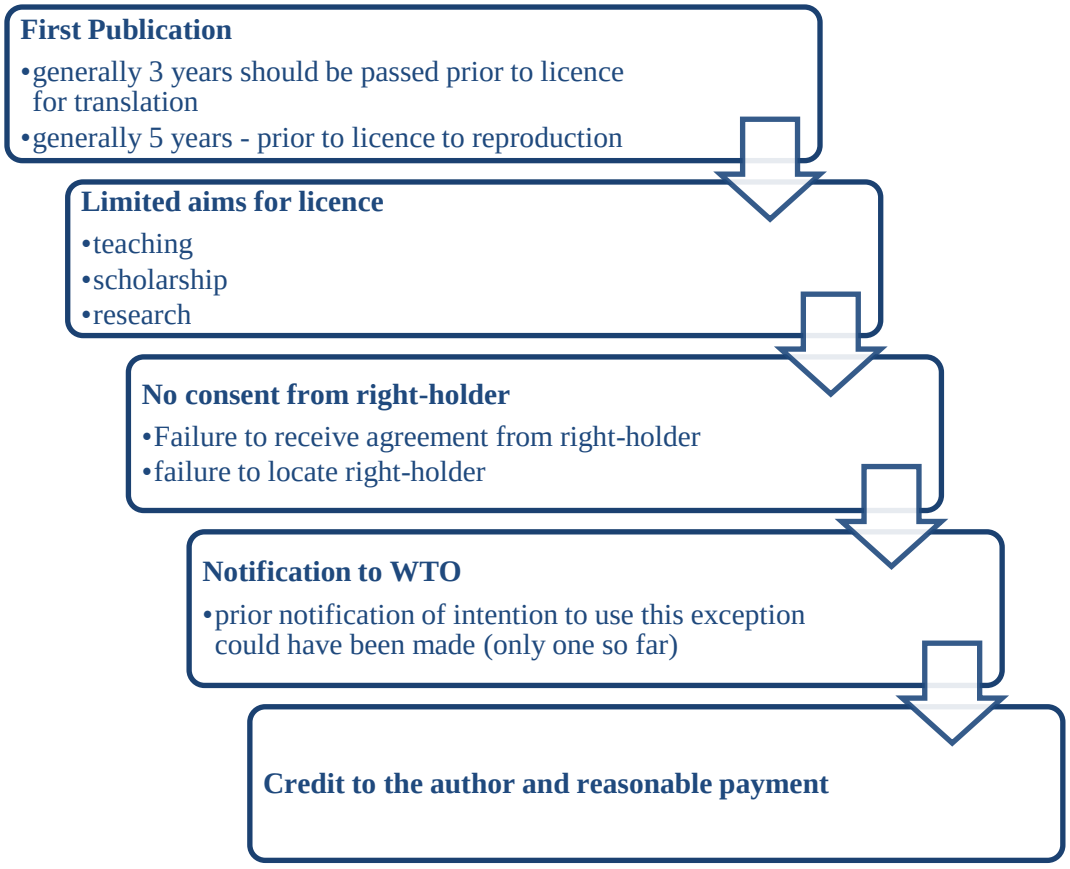

Figure 3. Brief and most relevant procedural steps for issuing CL in Copyright according to Berne Appendix.[82]

Although the CL in Copyright was so relevant that it found itself in the text of the Berne Convention, it has not yet been used fully, few countries have notified WIPO on their intention to use the Appendix and even fewer have demonstrated intent to the TRIPS Council that they are availing themselves to make use of the Appendix provisions.[83] Hence, the scholars condemn the Appendix as imposing

[82] See the Berne Appendix, *supra* 81. The chart is quoted from the Paper written for Lund University course Human Rights Perspectives on Intellectual Property Law (JAMR26). Urushadze Irine, *Does Copyright Protection Hinder Access to Education?* 2014. Unpublished, with the author. p. 4.

[83] Notifications for Berne Convention, including the Berne Appendix to the WIPO can be viewed here (some notifications on availing the facilities provided by the Appendix are following 79, 91, 232-240, 245, 249, 256, 262, 265, 266, etc):
http://www.wipo.int/treaties/en/ShowResults.jsp?country_id=ALL&start_year=ANY&end_year=ANY&search_what=N&treaty_id=15 [last accessed on May 26, 2015].
Notifications for Berne Convention, including the Berne Appendix to the TRIPS Council can be viewed here:
https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(@Symbol=%20ip/n/5/*)

impediments to the building of local publishing or to translation of textbooks to the minority languages.[84]

Although practice on Berne Appendix is almost nonexistent, it does not mean that countries do not engage in CL of Copyrighted works. Georgia for instance has applied a scheme that has allowed it delivering textbooks to every student in public schools at all levels and schoolchildren belonging to vulnerable groups in private schools.[85]

Georgian Law recognises classification of the textbooks, which means that for approving textbooks to be used at any school level education, they need to go through certain procedures.[86] As a part of the process a commission revises the textbooks and as of 2013 Publishing Houses or other copyright owners need to submit prior consent for reproduction of the textbooks and electronic versions of the protected materials in order to go through approval.[87] There are two types of licences that are allowed by Georgian Copyright Regime and textbooks can be subjected to both, in case of pressing social need.[88] The Ministry of Education and Sciences is authorised to grant common or special licences to third parties and in case of common licence, those third parties are obligated to pay the copyright owner 10% of the circulation price.[89]

For the past two academic years a JSC "United Georgian Publishing House" was selected as a third party who printed all the textbooks as a result of contract from the Ministry.[90] The Publishing Houses that were rightholders in this case are

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&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true# [last accessed on May 26, 2015].

[84] Chon Margaret in *supra* 64. quoting Basamalah, S. *Compulsory Licensing for Translation: an Instrument of Development?"* IDEA. vol. 40, no.4, pp 503-548. at p. 230.
Also Štrba Susan Isiko, *A Model for Access to Educational Resources and Innovation in the Developing World.* In *Intellectual Property, Trade and Development: Strategies to Optimize Economic Development in A TRIPS-Plus Era*, 2nd Edition, ed. by Gervais Daniel J. Oxford University Press, 2014. pp. 301-302.

[85] Statement from Ministry of Education and Sciences of Georgia. Available in English here: http://www.mes.gov.ge/content.php?id=4543&lang=eng [last accessed on May 26, 2015]. News Report Ekaterine Tukvadze, *Million and a Half School Pupils Will Receive Free Educational Materials This Year,* Medianews.ge, July 24, 2014. Available in Georgian here: http://medianews.ge/index.php/ka/print/83209/ [last accessed on May 26, 2015].

[86] The Order of Minister of Education and Science of Georgia on "Procedure and Pricing for Approving Textbooks for General Education Institutions". Order No. 30/ნ, February 25, 2011. Codified version in Georgian available at: http://www.mes.gov.ge/uploads/GRF%20wesi-kodificirebuli-12.09.2013.doc [last accessed on May 26, 2015].

[87] *ibid.* article 6.1.

[88] *ibid.* article 10.1.

[89] *ibid.*

[90] See News Report by Ekaterine Tukvadze, *supra 85.* Also, process and political results are available in news story by Natia Vakhtangashvili, *Are Free Textbooks Free?* Forbes.ge, in

claiming that their IP Rights were infringed and have ongoing trials in Georgian Courts.[91] The Publishing Houses are also claiming that the regulations are against the Constitution of Georgia, which is one of the rare constitutions directly recognising IP Rights: "The right to intellectual property shall be inviolable".[92]

The described procedure has not been taken according with the Berne Appendix regulations, but to make use of Berne or TRIPS regime there has to be international trade involved, while in this case regulations are not concerning on the import of textbooks, but only on the domestic publishers.[93] At the same time, it has to be taken into account, that differently from Berne Appendix, Georgian Regulations include a step where Publishers willingly give consent for future licensing of the textbooks, while Berne procedure rests upon the concept of failed negotiations. Therefore, this is not a typical Compulsory Licensing. However the publishing houses argued that this is forcing a hand to them, since if they don't go through the classification procedure, their textbooks cannot be used in any school and the IP Lawyers in Georgia argue that this does not constitute a difference, but the violation of CL rules recognised by Berne.[94]

The procedures established by Georgian Law have been operational for the past two academic years and, so far, no court has made any decision against it. At the same time, no international judicial process has started. Although Georgian market is substantially small for international publishing houses, since very few books are licensed and most are created domestically, the interest from those big international publishing houses might still be peaked as they would not be willing to risk exporting of these regulations to any other country. The Licensing scheme that works in Georgia has definitely saved many families from vast expenditures in textbooks. According to Ministry of Education each pupil needed books for

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Georgian. July 17, 2014. http://forbes.ge/news/355/aris-Tu-ara-ufaso-ufaso-saxelmZRvaneloebi%3F [last accessed on May 26, 2015].

[91] See Article by edu.aris.ge *Free Textbooks, Reality or a Tax Postponed by One Year.* May 22, 2014. Available in Georgian: http://edu.aris.ge/news/ufaso-saxelmZRvaneloebi-realoba-Tu-erTi-wliT-gadavadebuli-gadasaxadi.html [last accessed on May 26, 2015].

[92] Constitution of Georgia. Article 23. August 24, 1995. Available in English, official translation: https://matsne.gov.ge/en/document/view/30346 [last accessed on May 26, 2015].

[93] I have noted in my previous Paper that some textbooks were published in Georgia by the Licensees of foreign Publishing Houses, such as Oxford University Press, Pearson, Macmillan Education etc. Full list of Classified Textbooks are available in Georgian on the webpage of Ministry of Education and Sciences: http://www.mes.gov.ge/content.php?id=4839&lang=eng [last accessed on May 26, 2015].
See Paper written for Lund University course Human Rights Perspectives on Intellectual Property Law (JAMR26). Urushadze, Irine. *Does Copyright Protection Hinder Access to Education?* 2014. Unpublished, with the author. pp. 6-7.

[94] See Zakashvili Lika, *Free Textbooks at the Expense of Publishers.* April 15, 2013. Available in Georgian: http://www.liberali.ge/ge/liberali/articles/114544/ [last accessed on May 26, 2015].

around GEL 100-160 (approx. EUR 40-70).[95] While subsistence minimum for an average family is around GEL 270 (approx. EUR 110).[96] However the cornerstone of this scheme is publishing capacities, which are so lacking in many Developing countries and particularly LDCs.[97]

c. Trademark and Tobacco

As mentioned above, the IP rights can roughly be divided into two groups - invention boosters and informative rights. Trademarks are not the type of IPs that contributes highly to technological advancements, at least not directly, but they have high value in attributing product with its producer and thus allowing consumers to differentiate goods. The literature on the relationship of trademark and sustainable development is scarce, however it does affect economic development, as strong trademark protection enables more FDIs to the countries.[98] Professor Gervais suggests that "legal protection of marks gives companies an incentive to invest in making their marks more recognisable and easier to remember."[99]

Although Trademark might not seem as a relevant actor in IP-Development debate, the recent prominent discussion of Australia's Tobacco Plain Packaging Act has brought Trademark to the Agenda as well. It is undebated that Health plays important role in Development Agenda and the Act is heavily relied on public health issue.

The TPP requires "all tobacco products sold, offered for sale, or otherwise supplied in Australia [to] be in plain packaging",[100] which means that all tobacco products must contain graphic warnings for health dangers and no trademark can be displayed on the package.[101]

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[95] See *supra* 85.
[96] See data by National Statistics Office of Georgia. http://geostat.ge/cms/site_images/_files/english/households/Subsistence-minimum.xls [last accessed on May 26, 2015].
[97] See Helfer, Austin. *supra* 45. *at* pp. 349-355 quoting UNESCO report *Textbook and Learning Materials* (2000) to demonstrate other impediments beyond IP Regime to access to textbooks.
[98] See *Intellectual Property Rights, Development and Catch-up. An International Comparative Study.* ed. Odagiri Hirouki, Goto Akira et al. Oxford University Press. 2010. pp.6-7.
[99] Gervais, *Intellectual property, Trade and Development: The State of Play. Supra* 32. p. 521.
[100] Webpage of the Department of Health of Australia. http://www.health.gov.au/internet/main/publishing.nsf/Content/tobacco-plain [last accessed on May 26, 2015].
[101] More details are available in the Guide for Manufacturers / importers/ suppliers of tobacco products. 2014. Available online here:

The image displays an example of the TPP (intentionally selected the least graphic image).[102] The research has already demonstrated that plain packaging has reduced appeal of smoking to young people. The packaging represents dark colour packages with real images of tobacco-caused diseases, hence the consumers, particularly young ones believe that cigarettes:

- are less appealing;
- won't taste as good;
- are of lower quality;
- are smoked by less stylish and sociable people.[103]

Research also suggests that smokers associate taste and safety to the colour of the packaging, considering light coloured packs to taste better, have less tar and be safer.[104] Removing colour and trademark would make the appeal degrade particularly in terms of attractiveness, since plain packs are perceived as less attractive, exciting, fashionable, cool and stylish.[105] Studies also suggest more evidence that consumers claim plain packs to make them quit or at the very least help them do so.[106]

The Tobacco Plain Packaging Act provides the following objectives of the law:

a) to improve public health by:

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http://health.gov.au/internet/main/publishing.nsf/Content/tppbook [last accessed on May 26, 2015].

[102] The image is taken from *Examples of Plain Cigarette Packaging Required by Australia*. http://global.tobaccofreekids.org/en/examples_of_plain_cigarette_packaging [last accessed on May 26, 2015].

[103] See *Plain Packaging of Tobacco Products: A Review of the Evidence*. Prepared by Quit Victoria, Cancer Council Victoria. May 2011. pp. 11-16. http://www.cancer.org.au/content/pdf/CancerControlPolicy/PositionStatements/TCUCCVBkgrndResrchPlainPak270511ReEnd_FINAL_May27.pdf [last accessed on May 26, 2015].

[104] See *ibid*. p. 14. also Grimes Anthony, Doole Isobel, *Exploring the Relationship Between Colour and International Branding: A Cross Cultural Comparison of the UK and Taiwan*, Journal of Marketing Management, Vol. 14(9), 1998. pp.799–817. Romaniuk Jenni, *Brand Attributes – 'Distribution Outlets' in the Mind,* Journal of Marketing Communications, Vol. 9(2), 2003, pp. 73–92.

[105] See Moodie Crawford and others. *Plain Tobacco Packaging: A Systematic Review*, University of Stirling, 2012. pp. 84-85. http://phrc.lshtm.ac.uk/papers/PHRC_006_Final_Report.pdf [last accessed on May 26, 2015].

[106] See *ibid*. pp. 74-75.

i. discouraging people from taking up smoking, or using tobacco products; and
ii. encouraging people to give up smoking, and to stop using tobacco products; and
iii. discouraging people who have given up smoking, or who have stopped using tobacco products, from relapsing; and
iv. reducing people's exposure to smoke from tobacco products; and

b) to give effect to certain obligations that Australia has as party to the Convention on Tobacco Control."[107]

The Trademark owners have challenged this decision in numerous ways, starting at the National Level - at the High Court of Australia, where they have been defeated.[108] The court also underlined that the harm of tobacco products were not contested: "It is not in contest that smoking tobacco is a cause of serious and fatal diseases such as lung cancer, respiratory disease and heart disease and that the risk of contracting such diseases is reduced by quitting smoking. The use to which tobacco products are generally to be put after retail sale is smoking."[109]

Now the dispute has been moved to WTO DSB, where Ukraine, among other complainants, claims that Australia's measures, especially when viewed in the context of Australia's comprehensive tobacco regulatory regime, appear to be inconsistent with number of WTO Administered treaties, particularly with TRIPS.[110]

As mentioned above, interpretation of the TRIPS Agreement should be made by considering object and purpose of the treaty.[111] "[A] treaty interpreter is required to have recourse to context and object and purpose to elucidate the relevant meaning of the word or term. This logical progression provides a framework for proper interpretative analysis. At the same time, it should be kept in mind that treaty interpretation is an integrated operation, where interpretative rules or

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[107] Tobacco Plain Packaging Act 2011. No. 148, 2011 as amended. Sec. 3. http://www.comlaw.gov.au/Details/C2013C00190 [last accessed on May 26, 2015].

[108] The main argument from rightholders that the Act was an acquisition of property was not shared by the Court. JT International SA v Commonwealth of Australia, British American Tobacco Australasia Limited v The Commonwealth. High Court of Australia Judgement. HCA 43, 5 October 2012. S409/2011 & S389/2011. para 42.

[109] *ibid.* para 254.

[110] Dispute DS434. *Australia — Certain Measures Concerning Trademarks and Other Plain Packaging Requirements Applicable to Tobacco Products and Packaging.* Summary to date. https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds434_e.htm [last accessed on May 26, 2015].

[111] VCLT article 31. S*upra* 34.

principles must be understood and applied as connected and mutually reinforcing components of a holistic exercise."[112]

The relevance of the article 8 of the TRIPS agreement was underlined above, therefore while interpreting the scope of intellectual property rights, the goal of protection of public health should be cardinal.[113] "The key function of Article 8 is its relevance to interpreting the object and purpose of the TRIPS Agreement […]. The public health objective in Article 8 is relevant to interpreting what amounts to unjustifiably encumbered [according to Article 20 of the TRIPS]. **What is meant by 'public health' may require consideration of non-WTO sources, and, in that context, a source outside the WTO that is relevant to the meaning of public health is the FCTC and its Guidelines** [emphasis added]."[114]

FCTC in an Agreement under the WHO regime, which provides obligations for signatories to take measures that will make tobacco products less appealing and raise awareness on its dangers.[115] The Guidelines of the FCTC require member states to enact Plain Packaging Laws.[116] The relevance of Doha Declaration in this case is even greater.

Experts in constitutional and Intellectual Property law suggest that trade agreements permit governments to restrict use of trademarks to protect public health and that plain packaging is not an acquisition of intellectual property, it simply represents restriction of the use of marketing tools on cigarette packages.[117] At the same time, if we look at the wording of the TRIPS Agreement regarding Trademark, it is obvious that TRIPS grants only negative rights to "prevent all third parties" from using the mark.[118] "TRIPS Agreement generally frames trademark and other IP rights as negative rights precisely to allow

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[112] Appellate Body Report, *United States – Continued Existence and Application of Zeroing Methodology*, WT/DS350/AB/R/ February 4, 2009. para. 269.
[113] See Howse Robert, *The Canadian Generic Medicines Panel. Supra* 49, p.504.
[114] Frankel Susy, Gervais Daniel, *Plain Packaging and the Interpretation of the TRIPS Agreement,* 4 VUWLRP 1/2014. p.59. available at: http://ssrn.com/abstract=2234580 [last accessed on May 26, 2015].
[115] World Health Organisation. *WHO Framework Convention on Tobacco Control* (FCTC), adopted by the 56th World Health Assembly, May 21 2003. Articles 11 and 13. Full text available at: http://www.who.int/fctc/text_download/en/ [last accessed on May 26, 2015].
[116] See Guidelines for Implementation of Article 11 of the WHO FCTC on "Packaging and labeling of Tobacco Products" (decision FCTC/COP3(10)) and Guidelines for Implementation of Article 13 of the WHO FCTC on "Tobacco advertising, promotion and sponsorship" (decision FCTC/COP3(12)). Available from: http://www.who.int/fctc/guidelines/adopted/en/ [last accessed on May 26, 2015].
[117] Davison Mark, *Plain Packaging of Cigarettes: Would it Be Lawful?* Australian Intellectual Property Law Bulletin 2010; 23(5):105–8.
[118] TRIPS article 16.1. Also see Voon Tania, Mitchell Andrew, *Face off: Assessing WTO Challenges to Australia's Scheme for Plain Tobacco Packaging,* 22 Public Law Review 218. 2011. p. 13. Marsoof Althaf, *The TRIPs Compatibility of Australia's Plain Packaging Legislation*, The Journal of World Intellectual Property, Vol. 16, no. 5 – 6, 2013. p. 202.

Members to pursue legitimate non-IP-related public policies such as promoting public health".[119]

Therefore, the Tobacco Plain Packaging Act of Australia is another tool that is justified by IP regime and provides already efficient means to protecting public health. It has been operational for merely 3 years (TPP Act is in force since 2012), and several studies have deemed it efficient and proportionate measure. The WTO DSB Panel has been composed in May 2014 and it is expected to deliver its long-awaited report during the first half of 2016.[120]

Although TPP is not a *flexibility* directly recognised by the TRIPS Agreement, it brings us back to underlining the relevance of the object and purpose of the Agreement, which on its own is an overarching tool for the whole Agreement to be more flexible when States need to pursue their specific interests. However, it has to be noted that other countries were not capable of following Australia's path since "Big Tobacco" employs pressure and legal threats.[121]

d. Geographical Indicators – a Tool of Its Own

This thesis has so far discussed the *flexibilities* included in the IP Regime, which allow member states to enhance their pro-development goals without violating IPRs and their international obligations. It was noted above, that IP Rights are themselves created for promotion of innovation, inventiveness and technological progress. Geographical Indications are the type of IPRs which can be used for advancing development on their own.

GIs are relatively new IPRs, they are place names or words associated with a place used to identify the origin and quality, reputation or other characteristics of

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[119] Voon, Mitchell, *Face off. Supra* 118. p. 15. Referring to Panel Report, *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs, Complaint by Australia*, WT/DS290/R. April 20, 2005. n 125 at 7.246.

[120] See Summary of the Dispute. *supra* 110.

[121] Examples of Big Tobacco "aggressive" tactics include following: JT International is making legal threats towards Irish Government. See Beesley Arthur, *Tobacco Giant Issues Legal Threat Over Plain Packaging*, February 17 2015. http://www.irishtimes.com/news/politics/tobacco-giant-issues-legal-threat-over-plain-packaging-1.2106300 [last accessed on May 26, 2015].
"The world's largest tobacco company has warned the Government the introduction of plain packaging for cigarettes could lead to "an extremely high price" of compensation being paid to multinational tobacco companies by the taxpayer." Kelly Fiach, *Tobacco Giant Says Plain Packaging Could Lead To State Compensation*, 27 November 2013. http://www.irishtimes.com/news/health/tobacco-giant-says-plain-packaging-could-lead-to-state-compensation-1.1608508 [last accessed on May 26, 2015].
British American Tobacco make legal threats towards Namibia. See Heita Desie, *Namibia: Tobacco Firm Threatens Lawsuit*, December 16 2011, http://allafrica.com/stories/201111160892.html [last accessed on May 26, 2015].

products.[122] The aim of the GIs is to associate quality, reputation or other characteristics with the product. On its own it's somewhat similar to the concept of Trademark, as the latter is also an informative IPR, but main difference lies with the users' rights. In case of Trademark, the owner of the mark has exclusive right to use it and enjoy protection, while in case of GIs, it stands with a product and is associated with any given product from that place, despite the person or company that enjoys usage at that time. Simultaneously, Trademark has visual side of protection, while GIs are only word marks and visual qualities are not relevant.[123] There are several regimes aimed at protecting geographical names - *indication of source*, *geographical indication* and *appellation of origin*.[124] These three concepts have predeceased the TRIPS Agreement, which introduced term GI and protects it in quite limited manner, due to high tension negotiations prior to its adoption.[125]

TRIPS Agreement provides general protection to GIs and additional protection for Wines and Spirits.[126] However, this does not limit GI application to other, especially agricultural products and if we recall the narratives behind TRIPS negotiations, where agriculture was the main topic for Developing Countries. We shall see how relevant GIs can be for economic development of those countries. According to a recent study from International Trade Centre, out of 10 000 protected GIs with estimated trade value of over US$50 billion, around 10% is from developing countries.[127] "Champagne", "Cognac", "Tequila" are few most know GIs protected today, but there are other agricultural and not only agricultural products protected:

> "A GI may also highlight specific qualities of a product that are due to human factors found in the product's place of origin, such as specific manufacturing skills and traditions. That is the case, for instance, for

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[122] Definition of GIs can be found on the webpage of the WTO https://www.wto.org/english/tratop_e/trips_e/gi_e.htm [last accessed on May 26, 2015].
[123] For more details on the difference between GIs and Trademarks, see Presentation by Mr. Adargelio Garrido de la Grana. *Geographical Indications and Trademarks: Combined Efforts for a Stronger Product Identity*. International Symposium on Geographical Indications. World Intellectual Property Organisation (WIPO) and the State Administration for Industry and Commerce (SAIC) of the People's Republic of China. Beijing, June 26 to 28, 2007. WIPO/GEO/BEI/07/4. pp. 2-3.
[124] *ibid.* p.2.
[125] See CIPR Report. *supra* 42. pp. 87-88.
[126] TRIPS Agreement. Articles 22-23.
[127] Giovannucci Daniele et al. *Guide to Geographical Indications. Linking Products and Their Origins.* International Trade Centre. 2009. p. xvii. Available at: http://www.intracen.org/Guide-to-Geographical-Indications-Linking-Products-and-their-Origins/ [last accessed on May 26, 2015].

handicrafts, which are generally handmade using local natural resources and usually embedded in the traditions of local communities."[128]

This wide understanding of GIs holds promises not only for the producers and users, but also for rural area development and thus public at large. Although today Developed countries exercise GI protection more, this does not mean that GIs cannot be useful for Developing world too. Some very successful cases from India, Mexico, Colombia and other developing countries prove this point.[129] This does not entail that GIs should be overestimated. The Figure below demonstrates few relevant points:

Consumer Benefits	Owner Benefits
Higher quality and unique products for consumers available and encouraged	Higher prices for producers
Conveys messages and minimises "search costs"	Protection of local tradition and cultural practices
Producer or manufacturer liability more easily determined and secured (traceability)	Market for differentiation and exclusivity
Can provide a means by which universal values (cultural, traditional, environmental) may be preserved via market mechanisms	Positive local externalities including better employment, rural development, governance, etc.
Consumer Harm	**Owner Harm**
Exclusivity may elevate costs	Higher costs of production
May reduce innovation or improvement	May reduce innovation
Public GI systems increase public costs of governance	Likely to require greater local governance and institutional capacity and costs
May reduce competition and increase protectionism	If not state-run, will elevate costs of legal protection

Figure 4. How GIs can benefit or harm[130]

GIs thus have high potential of being useful for development and despite the risks or costs that might exist; it is still a possibility for Developing Countries and LDCs. According to WIPO Guide to GIs, they have high value to rural

[128] *Geographical Indications: An Introduction.* WIPO. 2013. http://www.wipo.int/edocs/pubdocs/en/geographical/952/wipo_pub_952.pdf [last accessed on May 26, 2015].
[129] See *supra* 127. pp. 145-207.
[130] Figure is taken from ITC Report. *Supra 127.* p. 20.

development by creating jobs, generating income and promoting a region altogether.[131]

Some studies demonstrate following reasons for providing GI protection:

- ✓ Improving access to markets;
- ✓ Preserving biodiversity and preventing bio-piracy;
- ✓ Protecting traditional 'know-how';
- ✓ Supporting community or collective rural development initiatives;
- ✓ Reducing market price fluctuations;
- ✓ Improving market governance (labelling and fraud rules, standards, traceability).[132]

GIs are relevant due to their capacity to provide benefits for direct economic growth and other socio-cultural values as well. As suggested by the International Trade Centre report, GIs can result in increased employment and higher income to the region, but at the same time - improve local governance, raise tourism and recognition and others.[133]

GIs have particular weight for smaller enterprises or especially farmers, which lack the capacity to brand their products.[134] These entities can make use of the GIs that are easier for them to register and the impact has been proven to be extremely advantageous increasing demand and higher retail price of the product, thus higher financial gains for producers; raising land value in the region and increasing socio-economic development and sustainability.[135]

TRIPS Agreement, as mentioned above, provides very general protection for GIs, with exception of wine and spirits. However, it does not mean that all other products cannot enjoy the protection and developing countries can themselves open the door to their products by providing such protection. However, they should be firm in their dedication to protecting the GIs originated from their countries, the *Basmati Case* demonstrated that reluctance to seeking legal enforcement for GIs might result in losing the benefits of the protection.[136]

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[131] See *supra* 128, p. 17.

[132] See Giovannucci Daniele et al. *Guide to Geographical Indications. supra* 127. Quoting broad-based, multi-year research conducted in EU by Sylvander Bertil and Allaire Gilles. WP3 Report. *Conceptual Synthesis – Task 1. Strengthening International Research on Geographical Indications (SINER-GI) project.* 2007.

[133] See *ibid.* p. 31.

[134] See *Geographical Indications for Development.* Case Study of Chinese Pinggu Peaches, available at WIPO webpage: http://www.wipo.int/ipadvantage/en/details.jsp?id=2595 [last accessed on May 26, 2015].

[135] *ibid.*

[136] See CIPR Report cited *supra* 42. p. 89. According to the case history, Basmati rice which was associated with a specific region was not protected by GIs and thus resulted in Rice breeding

3. How IP-Oriented Institutions Would React to these Flexibilities?

a. Do the Flexibilities and Other Tools Have a Chance in WTO DSU?

The *flexibilities* and other tools discussed in this thesis are suggested from reading the IP Norms. However, the bigger question is if countries desire to use them, would these tools have standing in the adjudicating bodies. This thesis tried to argue that *flexibilities* are all part of the TRIPS agreement and thus are allowed for the member states to use them. However, each of them is strictly limited and need to be evaluated on case by case basis, proving that public interests are higher than individual interest of IP Right-holder. It is important to look at the WTO DSU system as a political instrument as well, since the final decision is in the hands of the WTO Member States.[137]

b. How Does WTO DSU Work?

The World Trade Organisation's "charm" is its power to enforce its regulations, which is vested in the Dispute Settlement mechanism it has. It makes WTO laws one of the most efficient international instruments. The DSU is considered a central pillar of the organisation and the "settlement" term is usually underlined the most, as the system is oriented on settling disputes rather than judging them, which is somewhat a last resort.[138]

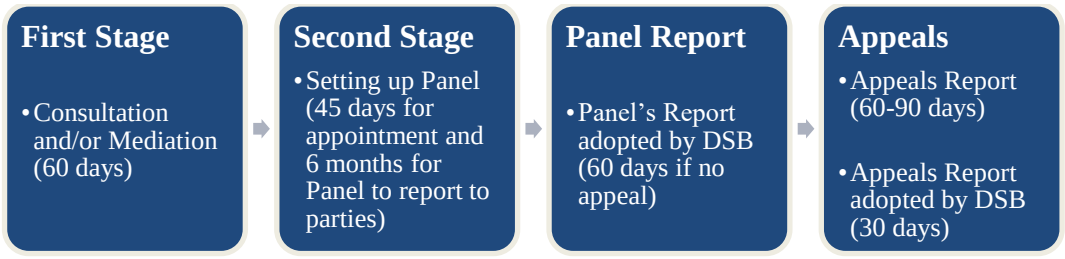

Figure 5. Main steps of WTO Dispute Settlement

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corporation securing trademark and benefiting from brand "Basmati" without producing rice in the original region.

[137] "As a result of the increased importance of WTO jurisprudence and the rigidity of the WTO political process, those governments that are able to participate most actively in the WTO dispute settlement system are best-positioned to effectively shape the law's interpretation and application over time." Shaffer Gregory, *Recognizing Public Goods in WTO Dispute Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection,* Journal of International Economic Law Vol. 7(2), 2004. p. 470. 2004. Based on Shaffer's argument Prof. Yu suggests to "take advantage of the WTO Dispute Settlement Process" for Developing countries. See Yu, *Trips and Its Discontents, supra* 31. pp.392-396.

[138] The web-page of the WTO. https://www.wto.org/english/thewto_e/whatis_e/tif_e/disp1_e.htm [last accessed on May 26, 2015].

The stages according to the Understanding on Rules and Procedures Governing the Settlement of Disputes are:

• Before the first hearing: each side in the dispute presents its case in writing to the panel.

• First hearing: the case for the complaining country and defence: the complaining country (or countries), the responding country, and those that have announced they have an interest in the dispute, make their case at the panel's first hearing.

• Rebuttals: the countries involved submit written rebuttals and present oral arguments at the panel's second meeting.

• Experts: if one side raises scientific or other technical matters, the panel may consult experts or appoint an expert review group to prepare an advisory report.

• First draft: the panel submits the descriptive (factual and argument) sections of its report to the two sides, giving them two weeks to comment. This report does not include findings and conclusions.

• Interim report: The panel then submits an interim report, including its findings and conclusions, to the two sides, giving them one week to ask for a review.

• Review: The period of review must not exceed two weeks. During that time, the panel may hold additional meetings with the two sides.

• Final report: A final report is submitted to the two sides and three weeks later, it is circulated to all WTO members. If the panel decides that the disputed trade measure does break a WTO agreement or an obligation, it recommends that the measure be made to conform to WTO rules. The panel may suggest how this could be done.

• The report becomes a ruling: The report becomes the Dispute Settlement Body's ruling or recommendation within 60 days unless a consensus rejects it. Both sides can appeal the report.

Figure 6. Stages of WTO Dispute Settlement Understanding[139]

[139] The process is taken from *Understanding the WTO*. World Trade Organisation. 2015. p. 57. available at: https://www.wto.org/english/thewto_e/whatis_e/tif_e/understanding_e.pdf [last accessed on May 26, 2015].
The text of the Agreement on *Understanding on Rules and Procedures Governing the Settlement of Disputes* is available at: https://www.wto.org/english/docs_e/legal_e/legal_e.htm#dispute [last accessed on May 26, 2015].

c. *Pro-Development Issues in The WTO Case Law*

TRIPS-related disputes are quite few in the WTO arena, with a little over 30 complaints making around 7% of all complaints filed.[140] When a state limits certain IP Rights based on the public needs, for instance, it might face a complaint at the WTO to resolve whether this limitation falls under the TRIPS Regime. This dispute would most likely come down to interpreting the TRIPS Agreement and that as described in previous chapter is done based on the VCLT.[141] Articles 7 and 8, the objectives and purposes of the TRIPS, are central for interpreting the Agreement. Around 15 decisions have necessitated interpreting the TRIPS provisions and in not so many cases the two articles mentioned above have been used.[142] Some Cases where TRIPS provisions were to be interpreted based on object and purpose of the Agreement are discussed briefly below.

■ Canada — Term of Patent Protection

The case dealt with the Canadian regulation granting different patent terms for the products based on when the patent application was filed. Specifically, those products that had been filed prior to October 1 1989 enjoyed protection of 17 years, while those filed after the date enjoyed term of protection of 20 years.

The case focused on the issue whether the TRIPS Agreement and its certain provisions had retroactive force and to what extent. The case in both Panel and Appellate Body dwelled mostly about interpreting the Agreement and the tools of interpretation. Object and Purpose of the Treaty was considered quite extensively, however neither the Panel nor the Appellate Body discussed articles 7 and 8, but the Appellate Body stated:

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[140] List of all complaints can be found on the webpage of the WTO: https://www.wto.org/english/tratop_e/dispu_e/dispu_status_e.htm [last accessed on May 26, 2015].
List of all complaints based on TRIPS Agreement is available here: https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/6_tabledscases_e.pdf [last accessed on May 26, 2015].

[141] The very second complaint in the WTO Dispute Settlement system came down to interpreting the GATT provisions and there the Panel and Appellate Body affirmed that VCLT rules have become customary international law, thus they should be used when adjudicating WTO cases. See *supra* 33 and 119.

[142] See Grosse Ruse–Khan Henning, *The (non) Use of Treaty Object and Purpose in Intellectual Property Disputes in the WTO*. Sustainable Development Principles in the Decisions of International Courts and Tribunals 1992-2012. Cambridge University Press, 2012; Max Planck Institute for Intellectual Property & Competition Law Research Paper No. 11-15. September 28, 2011. p. 33. Available at SSRN: http://ssrn.com/abstract=1939859 [last accessed on May 26, 2015].

> "we note that our findings in this appeal do not in any way prejudge the applicability of Article 7 or Article 8 of the TRIPS Agreement in possible future cases with respect to measures to promote the policy objectives of the WTO Members that are set out in those Articles. Those Articles still await appropriate interpretation."[143]

- **Canada Patent Protection of Pharmaceutical Products**

In this case Canadian Law allowed use of a patented product without right holder's consent in case of testing that was required by law for market approval. This regulation, the so-called "regulatory review exception" or "bolar exception" was permitting use of the product 6 months prior to the patent protection term (20 years) expiration. The reasoning behind the regulation was that it allowed competitors to enter the market right after the patent protection term was over. European Communities and their member States took the case to the WTO Dispute Settlement System and argued that Canadian regulation was against TRIPS Agreement.

The Panel discussed numerous issues, but for this thesis the most relevant is how it chose to interpret the TRIPS Agreement. The relevance of object and purpose was stressed out as well as other means of interpretation set out in articles 31 and 32 of the VCLT, such as finding ordinary meanings to the relevant terms, recalling *traveaux preparatoires* of the covered agreements, subsequent practice of the states and other tools. It must be noted, that Canada mainly referred to the articles 7 and 8, claiming that their regulations were justified by the public health interest the country had. The European Communities "did not dispute the stated goal of achieving a balance within the intellectual property rights system between important national policies". They did argue on whether Canadian regulations were achieving the goals included in the TRIPS regulations or was this something that did not fall within the scope of the Agreement, since Article 30 of the Agreement demanded measures to be "limited".

The Panel underlined, that the "limited" measures allowed by the Agreement can be used to deal with problems that may exist in specific product fields, these

[143] *Canada - Patent Protection of Pharmaceutical Products.* WT/DS170/AB/R, September 18, 2000. para. 101. available at: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds170_e.htm [last accessed on May 26, 2015].

permitted measures can be used for solving some important national policies referred to in Articles 7 and 8.1 of the TRIPS Agreement.[144]

■ EC - Trademarks and GIs

Australia and USA brought the case regarding European Union regulation, which provided higher protection to the GIs originated in Europe, thus giving less protection to the IP Rights originated from outside Europe, including the Trademarks. The issue at hand was whether these regulations were violating the National Treatment principle enshrined in the TRIPS Agreement, which prohibits the member states to grant higher protection to the rights originated in their territories than those originated from beyond. The Panel had to decide whether different registration steps and certain procedural measures provided for non-EC originated products or nationals were in fact damaging the "effective equality of opportunities" between different nationals and products to the detriment of non-EC nationals and products. In this case the Panel and the Appellate body had to interpret certain provisions of the Agreement to define what the scope of the National Treatment and other issues is. The Panel underlined that VCLT rules should be used to make "an interpretation in good faith in accordance with the ordinary meaning to be given to the terms in their context and in the light of the object and purpose of the agreement. Recourse may be had to supplementary means of interpretation."[145]

The object and purpose was numerously underlined in the case, although no mention of article 7 was made: "The object and purpose of the TRIPS Agreement [...] includes the provision of adequate standards and principles concerning the availability, scope, use and enforcement of trade-related intellectual property rights. This confirms that a limitation on the standards for trademark or GI protection should not be implied unless it is supported by the text."[146] Article 8 came into the attention of the Panel which stated:

> "[The principles set out in article 8] reflect the fact that the agreement does not generally provide for the grant of positive rights to exploit or use certain subject matter, but rather **provides for the grant of negative rights to prevent certain acts**. This fundamental feature of intellectual

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[144] See *Canada - Patent Protection of Pharmaceutical Products.* WT/DS114. quoted *supra* 33. paras 7.24-7.26 and 7.92.
[145] *EC - Trademarks and Geographical Indications.* WT/DS290/R. April 20, 2005. para 7.605. avaialble at: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds290_e.htm [last accessed on May 26, 2015].
[146] *Ibid.* para 7.620.

> property protection inherently grants Members **freedom to pursue legitimate public policy objectives** since many measures to attain those public policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement [emphasis added]".[147]

These cases demonstrate that Articles 7 and 8 although referred not so many times in the WTO case law still have high relevance and there definitely is an understanding that certain "legitimate public policy objectives" have standing.

d. What Has Changed since These Few Landmarks?

The three cases mentioned above are from 2000, 2001 and 2005 relatively. Few things have changed since they were adopted by the DSB:

- Doha Agreement had not been adopted at the time of adoption of the first two cases;
- Development Agenda of UN was coming into existence for the first two cases;
- WIPO Development Agenda has been adopted and WTO has started paying attention to Development much more since all three cases; and
- Human Rights mainstreaming has become more and more topical only quite recently.

These changes mean that the global policy before 2005 and afterwards was so different that all these three cases could have been looked at quite differently. However, TRIPS object and purpose and the right of member states to follow their public policy interests were still considered relevant, and the changes mentioned above would only strengthen their right. The main point here is that seeing TRIPS as a balancing tool and its object and purpose granting negative rights to prevent IP Rights abuse is not a novelty for the WTO and it would not be unimaginable for the disputes to be settled in a manner promoting these ideas in the future. Furthermore, the WTO will pay even more attention to these issues:

> "The importance accorded to [articles 7 and 8] in the Doha negotiations [,,,] may lead a [WTO] panel to take a longer look at how these provisions should be interpreted in the context of the Agreement as a whole, especially with respect to the need for 'balance'. A possible practical

[147] *Supra* 145. para 7.246.

impact of the Doha insistence of Arts 7 and 8 may serve as a basis for the interpretation of certain provisions of the Agreement."[148]

Falling back to VCLT rules of interpretation, Doha Declaration has also been considered a subsequent agreement between parties, since the WTO case law already suggests that non-binding document can also constitute such an agreement.[149]

It has to be noted that the tension between public policy and private interests of IP Right-holders have not been as tense as it is now arisen from the Australian Tobacco Plain Packaging Act. This case will have to deal with public health policy goal very extensively and the panel will be faced to interpret TRIPS Agreement based on the object and purpose, considering all the changes mentioned above, in light of the Doha Declaration, Development Agendas and others. Even though none of these tools are legally binding, they will have high value as arguments from the parties and the Panel cannot avoid giving them certain significance.

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[148] Gervais Daniel J, *The TRIPS Agreement: Drafting History and Analysis*, 2nd edition. 2003. London. page 120.

[149] See Frankel Susy, *WTO Application of 'The Customary Rules of Interpretation of Public International Law' To Intellectual Property*, Virginia Journal of International Law, 46(2). pp. 413-414 quoting *United States - Section 110(5) of the U.S. Copyright Act.* WT/DS160/R. The Panel in this case considered WIPO Copyright Treaty as a subsequent development, even though the document was ratified only by small number of countries and was not entered into force. The Panel noted: "We note that the subsequent developments just mentioned do not constitute a subsequent treaty on the same subject-matter within the meaning of Article 30, or subsequent agreements on the interpretation of a treaty, or subsequent practice within the meaning of Article 31(3) [of the VCLT]. Thus such subsequent developments may be of rather limited relevance in the light of the general rules of interpretation as embodied in the Vienna Convention. However, in our view, the wording of the WCT, and in particular of the Agreed Statement thereto, nonetheless supports, as far as the Berne Convention is concerned, that the Berne Union members are permitted to provide minor exceptions to the rights provided under Articles 11 and 11bis of the Paris Act of 1971, and certain other rights."
WT/DS160/R adopted on June 15, 2000 at para. 6.69. available from: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds160_e.htm [last accessed on May 26, 2015].

e. Three Hypothetical Cases - "What If"

Below I will try to depict three mock situations, where a member state of the WTO uses some of the *flexibilities* discussed in previous chapter. In all three cases I will discuss issues based on TRIPS Agreement only, domestic and TRIPS+ regimes are disregarded in order to keep the discussion in international IP Regime Arena. However global policy issues, such as Doha Declaration, WHO framework, UN or other Development Agendas will be considered as arguments.

■ Hypothetical Case 1: CL in Pharmaceuticals

Country A uses CL to export patent protected pharmaceuticals to Developing Country B without using Paragraph 6 solution.

In this hypothetical case I try to demonstrate what could happen if a Developed member of the WTO with high manufacturing capacities licensed a pharmaceutical product to a company that will export it to an LDC member state with limited or no manufacturing capacity without going through the so called "paragraph 6 solution" described in previous chapter. The disease that the product is used for is detrimental to global health and poses risk to the whole world if it is spread. Country A followed all steps required by the TRIPS article 31 - that is consultations with the product owner, which failed; the reasonable time has passed considering there was extremely urgent circumstances; the use was granted non-exclusively to a company willing to produce and export the product only to Country B and to the limit that the production (and the licence) will cease to exist once the Country B eradicates the disease to a reasonable level.

Firstly, in order the Country A to face legal remedies, there has to be a different member of the WTO who would bring the case to the DSB, however this is not hard to imagine, since many states are politically influenced by big companies, especially by those like Big Pharmaceuticals. The second issue is that the purpose of WTO DSU is more solutions than adjudications, hence the consultations and/or mediations would take the first stage of the dispute and the case might not even end up with the Panel. In case the countries do not reach a mutually satisfactory consultation or mediation results, then Panel would be comprised.

The Panel will have to deal with following legal issue: was Country A allowed to use Compulsory Licensing based on article 31 of the TRIPS Agreement? As discussed in the chapter above, the article prescribes certain preconditions to using CL. In this situation, since almost all requirements were followed by the Country A, the main problem is the paragraph "f" of the article: "any such use shall be authorized predominantly for the supply of the domestic market of the

Member authorizing such use". Which means that the Panel will be tasked to interpret what this provision means and based on the case law, including but not limited to the cases discussed above, object and purpose of the TRIPS Agreement will be looked at. At the same time, the Doha Declaration, WIPO Development agenda and UN Development Agenda cannot be disregarded since they can be seen as authoritative sources to understand what public policy interests exist.

The VCLT also provides for interpreting the Treaty based on its ordinary meaning and as it was underlined in the previous chapter, the wording of the Article 31.f does not fully prohibit using licensing for non-domestic markets. Since ordinary meaning of the word "predominantly" merely means "mostly", that with the object and purpose promoting public health goals among others, and the apparent readiness of the WTO DSB to take articles 7 and 8 to its well-deserved height, I suppose such a measure would be considered allowed under TRIPS Agreement. However, the preconditions are clear - these issues should be dealt with caution, based on each case's own merits and only in cases of certain exigent circumstances. The diseases threatening vast number of people, wherever the disease is, certainly places the case in the basket of "extreme urgency".

- **Hypothetical Case 2: CL in Educational Materials**

Country A uses CL on Copyrighted materials produced in Country B to translate them and make them available for free for vulnerable schoolkids.

In the second hypothetical case Country A with certain publishing capacities, despite its development level, decides to use Compulsory Licence on Copyrighted textbooks produced in Country B, but it avoids the complex procedures set out in the Berne Appendix. Country A, does try to negotiate with Copyright holders, awaits reasonable time from them; also tries to negotiate with its printing houses to create textbooks of their own based on ideas and not forms of expressions of the copyrighted products[150]. However there is limited capacity to do so and yet the statistics from the Country A suggest that schoolkids from primary and secondary levels are dropping out due to the lack of textbooks.

After Country A used CL on the textbooks it guaranteed that a notification was made and reasonable payment would also be made to the original right-holder. The textbooks were paid for from the state budget and distributed with a non-

[150] It has to be noted, that Copyright only provides protection for forms of expressions, while ideas are not protected, which means that in case a publishing house can create different form of expression based on ideas from a copyrighted product, there is no violation of the IPR.

commercial price to primary and secondary school pupils, i.e. the price of production and distribution only.

In a case where the copyright holder has high political influence, country B is very likely to bring the case to the DSU of the WTO. The case will focus on article 13 of the TRIPS Agreement, which provides: "Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder."

The Panel will have to interpret several issues, most importantly what is normal exploitation of the work and what are the legitimate interests of the rightholder. As mentioned above, the interpretation will be made based on customary international law, which is enshrined in the VCLT, so again the object and purpose will be considered. In this case the public policy interest Country A is trying to pursue is ensuring that the right to education is accessible to all. The UN Development Agenda is demanding on achieving universal primary education, but at the same time, it is undisputed how relevant education and closing the knowledge-gap is for multiple issues, including achieving the exercise of other rights and sustainable development of a state at large.

At the same time, the Panel will have to discuss whether the measures Country A took were limited to a special case. Considering that the CL was granted only for school pupils of primary and secondary level and it was not for commercial use, the case is apparently limited, and it is within the normal exploitation and the owner is rewarded reasonably, which is towards the right holder's legitimate interest.

It could be hard to argue that access to secondary education is as vital as access to primary education, however considering the relevance of education overall and the specific issues characteristic to the Country limiting the Copyright, it might still be justified. Thus this measure should be considered as promoting "the public interest in sectors of vital importance" to the socio-economic development of the Country A and is therefore in conformity with the TRIPS provisions.

- **Hypothetical Case 3: Tobacco Plain Packaging**

Country A adopts TPP to limit tobacco consumption.

In this case Country A, which has increasing statistics of tobacco related health problems, diseases and even deaths, considers implementing Tobacco Plain Packaging regulation, prescribed by the WHO FCTC and its soft-law instrument,

Guidelines to this Convention, specifically to the implementation of Article 11.[151] Specifically, Country A enacts a Law prohibiting the usage of any Trademark on the packaging of Tobacco products and requires all producers to use warning texts and images demonstrating tobacco-related diseases. The name of the company and brand can still be used but only as a regular text with no visual additions.

The Tobacco industry is one of the most powerful in the world, which means that several countries are likely to bring the case to the WTO DSU.[152] The main issue in dispute is whether the TRIPS Agreement provides a positive right to use Trademarks, or merely a negative right to prevent use from other parties. Article 16 only prescribes the negative right of the Trademark owner and TRIPS does not state anywhere that Trademark means the right to freely use it. However, the protection of the private interests of the right-holders should be efficient and without using the Trademark there is no use of having it at all, which destroys the right altogether. Therefore, the Panel will have to decide, which is more important - the private right to enjoy the benefits of the Trademark or the public health interest of Country A.

As demonstrated in the cases quoted above, interpreting the TRIPS Agreement will have to be made based on its object and purpose. Adopting "measures necessary to protect public health" is one of the principles of the Agreement, but at the same time, what can be considered in the public health scope has to be determined based on numerous things – the Doha Declaration, UN Development Agenda and the WHO Framework Convention should most certainly be considered here. The evidence of Tobacco being detrimental to health is overwhelming and the WHO, the primary health-oriented organisation, has been promoting different measures to limit tobacco consumption, including plain packaging. All this suggests that Country A is pursuing a very legitimate interest of public health and TRIPS almost certainly allows such measures.

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[151] The Guidelines can be found on the WHO Web-page: Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control (Packaging and labeling of tobacco products) available at: http://www.who.int/fctc/guidelines/article_11.pdf [last accessed on May 26, 2015].

[152] It is remarkable that Australia, who enacted such regulations, has faced complaints from 5 countries Ukraine, Honduras, Dominican Republic, Cuba and Indonesia. Some of which do not even trade with Tobaccos with Australia, Ukraine for example, is one of the biggest tobacco producers since some of JT International's and Philip Morris' factories are situated there, however it does not export tobacco products to Australia. See Australian Broadcasting Corporation's news report from April 17 2012 available here:
http://www.abc.net.au/lateline/content/2012/s3479769.htm [last accessed on May 26, 2015].
At the same time, Tobacco companies have been alleged to fund the State claims in WTO against Australia. See Martin Andrew, *Philip Morris Leads Plain Packs Battle in Global Trade Arena*, Bloomberg, 22 August 2013. http://www.bloomberg.com/news/articles/2013-08-22/philip-morris-leads-plain-packs-battle-in-global-trade-arena [last accessed on May 26, 2015].

Conclusion

The TRIPS Agreement is justly considered as a primary international document for the Intellectual Property Regime, but is it fair to consider it an instrument solely oriented on protecting Intellectual Property Rights?!

Common understanding suggests that the Intellectual Property Regime and the TRIPS Agreement in particular serves against the sustainable development goals in the world. This thesis proposes quite the contrary, or to be precise – that the TRIPS Agreement is a tool to balance out the private interests of IP right-holders and the public policy interests of States. Thus putting forward the idea that maybe IP Regimes serve or could serve development instead of hindering it.

Looking at the TRIPS Agreement of course it is senseless to say that it is not an instrument providing for the protection of Intellectual Property rights, because it surely is. But taking a closer look at certain provisions of the Agreement and analysing the text using customary rules of interpretation, it can be demonstrated that this Agreement can be easily used as a tool for enhancing some Sustainable Development goals that states, particularly the Developing or Least Developed ones have.

One should not forget what the concept of Intellectual Property is - it helps expand technological progress, innovation, stimulates invention, creates incentives to create cultural, educational and scientific work and so on. However History teaches us, that it also creates possibilities of abuse of these rights, "Patent Trolls" is not a recent example, inventors that have revolutionised science like Thomas Edison and James Watt exploited their intellectual property rights in a way that actually slowed down and crumpled innovation and progress.[153] The "Process of Development requires [a] careful mix of political reform, sound economic policies and the strategic exploitation of freely available technology, all operating within a legitimate socio-cultural framework."[154]

It is relevant to understand what we see within the meaning of Development as well. This thesis attempted to demonstrate certain policies that define Development, but it can be summarised in simple words as an idea that includes economic growth, human development and environmental sustainability. The first one can easily be achieved by technological progress, Transfer of Technology, as

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[153] See May Christopher, Sell Susan. *Forgetting History is Not an Option! Intellectual Property, Public Policy and Economic Development in Context*. Presented at: Intellectual Property Rights for Business and Society Birkbeck College, University of London. September 15, 2006. available at: http://www.dime-eu.org/files/active/0/MaySell.pdf [last accessed on May 26, 2015].

[154] Gana (Okediji), *The Myth of Development. Supra* 1. p. 332. Quoting Vogel Ezra F, *The Four Little Dragons: The Spread of Industrialization in East Asia,* Cambridge: Harvard University Press, 1991.

well as high protection of IP Rights. However considering that economic growth is merely a part of Development, it is clear that other aspects such as Human Rights, Democracy, Rule of Law, Climate Change, etc. should be taken into account. Today we understand Development as Freedom, however the Development as Growth debate has not disappeared and the IP Regime is almost unanimously considered a necessary tool to achieve Growth, however it is not considered to have the same effects in all contexts.[155]

The main point of this Thesis is not to find out whether the IP Regime can help or hinder Development. But rather how we can utilise the IP Regime, particularly the TRIPS Agreement to help Developmental Goals existing in the Global arena as well as those that have emerged locally in different countries.

Quite a handful of scholars suggest that the TRIPS rules can be used as ingredients to optimise knowledge and economic development and that it can be seen as a balancing tool between public and private interests.[156] This Thesis used customary rules of interpretation to explore the wording in the TRIPS provisions that could help use the Agreement as such a balancing Tool. Articles 7 and 8 of the Agreement definitely possess the highest power to do so. Existing case law, WTO member states subsequent practices, scholarly developments and Global Development discussions all demonstrate that the IP Regime includes certain instruments, often referred as *flexibilities* that can help countries achieve development. In certain cases, the IP Rights themselves can also be influential and useful for developing certain fields that are commonly viewed as diminished by the very IP Regime created by TRIPS (GIs in this case).

We should not forget that a number of economic studies suggest how trade reacts to different levels of IP Protection. Fink and Maskus demonstrated in their study in 2000 that weaker IP Protection leads certain industries to focus on importing goods to the country, instead of establishing production there, which happens more in countries with higher IP Protection.[157] However as mentioned above, economic variables are not the only thing that measure Development and sometimes certain sacrifices need to be made to address exigent circumstances such as health concerns, educational problems, etc.

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[155] "Sufficient IP protection is an essential component of increased inward FDI and trade flows in IP-sensitive goods for countries above a certain economic development threshold. […] Inward FDI is a more powerful economic development lever than trade. It transfers technology and usually creates jobs requiring a higher skill level. […] In the best-case scenario, some research and development jobs are created, which may have spillover effects in areas such as higher education, or local laboratories." Gervais, *supra* 32. pp.519-520.

[156] Gervais suggests that TRIPS rules can be used as ingredient to optimize knowledge and economic development. *Supra* 32. p. 525.

[157] See Fink, Maskus, *Intellectual Property and Development. Supra* 38. at pages 43, 55, 14, 159.

The relevance of the WIPO Development Agenda that focuses on Cooperation, Norm Setting, Education and Capacity Building cannot be undermined. It is extremely relevant that countries in need of facing their public policy interests know how to do so. This thesis suggested that the TRIPS normative content allows certain measures, but frequently countries in need of those measures are most reluctant to use them, in which case the role of UNCTAD and WIPO becomes more significant. When describing hypothetical cases, I suggested that the WTO Dispute Settlement Body has the possibility of leaning towards pro-development issues. However, it does not mean that IP Rights protection can be neglected, on the contrary, it merely suggests that when necessity and exigency demand, countries that will make use of the TRIPS flexibilities or any other tools, will most likely not face sanctions. But this needs to be done in line with certain requirements demanded by TRIPS and doing so for many countries might be hard, since it requires high proficiency in IP Regulations. UNCTAD and WIPO are equipped to provide legal or any other assistance to certain states and they are mandated to do so.

At the same time, one cannot neglect that apart from legal and economic issues, the IP Regime is very much tied to political tensions. IP Rights are not merely rights of individual inventors or creators; they mostly belong to big corporations with big power. Several cases nowadays demonstrate how politics in the WTO and even in the DSB is affected by such corporate powers. The Australian Tobacco Plain Packaging case discussed in the Thesis is a good demonstration, where Ukraine, one of the countries that brought the case to the DSB apparently does not even trade Tobacco with Australia. However, arguably, the influence of tobacco companies in the country made Ukraine take the action to the WTO system.[158] On the other hand, the same case will shed great light on the discussion posed in this thesis - whether TRIPS can be leaned towards public policy goals in a way that limits IP Rights to a quite high extent; and whether the object and purpose of the Agreement is indeed IP Right protection or reaching a balance between private and public interests.

Peter Yu suggested that articles 7 and 8 of the TRIPS Agreement, which are the result of compromises made during TRIPS negotiations can be a "blessing in disguise" of the Agreement, however "[w]hether the two provisions can become a

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[158] See *Supra* 152, articles demonstrating the tactics of Big Tobacco in pressuring States. At the same time, Tobacco Industry is not alone in spending money to protect its IP benefits. See Subramanian Sujitha, *The Changing Dynamics of the Global Intellectual Property Legal Order: Emergence of A 'Network Agenda'?* International and Comparative Law Quarterly, volume 64, Issue 01, January 2015. p. 136-137. Subramanian suggests that according to Senate Office of Public Records data, computer and internet industries have spent USD 125 million in 2011, while entertainment industry spend USD 122 million. Copyright, Patent reform and Privacy were the top issues of the lobby.

true blessing will depend on whether the WTO member states can use them effectively, to their advantage, and to the fullest possible extent."[159]

This thesis demonstrated a few ways of how these two articles can be "awakened" and utilised by the States or by the WTO and its Dispute Settlement Body to enhance the developmental goals that the countries face. Political will is primary requirement for doing so, the legal means do exist and countries need to tailor their regulations to their needs in a way that will balance the private rights of Intellectual Property Right-holders and the legitimate public policy interests of the Countries.

The suggestion of using *flexibilities*, among other things, is not a stretched thought. A few successful cases were brought up to prove this point and some ongoing ones will shed even more light on the debate, like the Australian TPP dispute in the WTO. At the same time, the growing Development discourse and Human Rights mainstreaming also demonstrate, that policies can be affected by them and countries have certain liberties to tend to their problems if needed. Blaming their international obligations including TRIPS for "tying their hands" cannot be a way out anymore. There is no necessity of amending the Agreement, especially considering the complexity of the amendment process. It might even be impossible (the still pending amendment on "paragraph 6 solution" is evidence to that), and neither is creating new documents needed. Adopting the Doha Declaration was required by the political power-tensions at a time, when some states were trying to promote public health interests but faced political barriers in the international arena. Thus reinstating the object and purpose and reminding member states of their rights was prompted. The wording and form of the expressions in the Doha Declaration prove that whatever was upheld by this document was already within the TRIPS Agreement and awakening its provisions, by interpretation or any other method, in a pro-development way is enough to achieve the legitimate goals the member states might face.

The aim of this Thesis was not to depict Intellectual Property rights as an evil, quite the contrary, these rights are necessary to create incentives for innovation and progress, but it is also true that their protection to a certain extent hinders free and full access to them, unless we consider the exceptions provided by the regime that also protects them. In order to completely rip the benefits of progress the protection of the rights and access to the objects of protection should be balanced. Demonstrating the ways of providing protection of the rights and access to those who need the objects of these rights was central to this Thesis.

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[159] Yu, Peter, *The Objectives and Principles of the TRIPS Agreement*. 2009. p. 36. available at: http://www.peteryu.com/correa.pdf [last accessed on May 26, 2015].

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